

**TO COMPARE THE IMPACT OF VARIOUS METHODS OF COUNSELING
ABOUT INHALERS IN ASTHMA AND COPD PATIENTS AND MEASURE
THE EFFECTIVENESS OF COUNSELING**



**Dissertation Submitted to
THE TAMILNADU Dr.M.G.R MEDICAL UNIVERSITY,
Chennai-600 032**

**In partial fulfilment of the requirements for the award of the Degree of
MASTER OF PHARMACY
IN
PHARMACY PRACTICE**

**Submitted by
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OCTOBER-2017**

Certificates

CERTIFICATE

This is to certify that the dissertation entitled “**To compare the impact of various methods of counseling about inhalers in asthma and COPD patient and measure the effectiveness of counseling**” submitted by **University Reg No. 261540657** is a bonafide work carried out by the candidate under the guidance of **Mr. Dr.V. Sivakumar M. Pharm., Ph.D**, and submitted to The Tamil Nadu Dr. M.G.R. Medical University, Chennai, in partial fulfillment of the Degree of **Master of Pharmacy in Pharmacy Practice** at the Department of Pharmacy Practice, PSG College of Pharmacy, Coimbatore, during the academic year 2015-2017.

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DECLARATION

I do hereby declare that the dissertation work entitled **“To compare the impact of various methods of counseling about inhalers to asthma and COPD patient and measure the effectiveness of counseling.”** submitted to The Tamil Nadu Dr.M.G.R. Medical University, Chennai, in partial fulfillment for the Degree of **Masters of Pharmacy in Pharmacy Practice**, was done by me under the guidance of **Dr.V.Sivakumar M. Pharm.,Ph.D.** at the Department of Pharmacy Practice, PSG College of Pharmacy, Coimbatore, during the academic year 2015 – 2017.

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EVALUATION CERTIFICATE

This is to certify that the dissertation entitled “**To compare the impact of various methods of counseling about inhalers to asthma and COPD patient and measure the effectiveness of counseling.**” submitted by **University Reg No. 261540657** the Tamil Nadu Dr. M.G.R. Medical University, Chennai, in partial fulfillment of the Degree of **Master of Pharmacy in Pharmacy Practice** is a bonafide work carried out by the candidate at the Department of Pharmacy Practice, PSG College of Pharmacy, Coimbatore and was evaluated by us during the academic year 2015-2017.

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Acknowledgement

ACKNOWLEDGEMENT

I would like to bring to light those who have helped me in the completion of my research work without which this work would not have reached its destination.

First and foremost, let me thank the **Almighty God**, whose grace has been with me at each step of this study without which no human achievement is possible.

My sincere thanks to my dear parents for their prayers, support and encouragement that made me possible to finish my study.

I would like to take this opportunity to acknowledge institution sources and individuals for their support and assistance in this academic endeavor.

In this very special occasion I would like to express my sincere thanks and heartfelt gratitude to my research guide **Dr. V. Sivakumar M.Pharm., Ph.D.**, Associate Professor, PSG College of Pharmacy, Coimbatore. I am very grateful for his support, and unwavering guidance from the beginning to the end of the dissertation work.

I would like to express my deep sense of gratitude to our respected Principal **Dr. M. Ramanathan, M.Pharm., Ph.D.**, for providing various facilities that made my dissertation work more ease. Without his support and help this dissertation would not have been possible.

For most I would like to express my sincere thanks to our beloved madam **Dr. Prudence A. Rodrigues M.Pharm., Ph.D.**, Head of the Department for her continuous support, patience and motivation to carry out this dissertation work.

I owe my deepest gratitude **Dr RM.PL Ramanathan MD. DM** Department of pulmonary medicine for his support and encouragement for my thesis work.

I am greatly thankful to **Dr .G Andhuvan, M.Pharm , Ph.D**, **Mrs. P.Rama, M.Pharm., (Ph.D)**, **Dr. Ashly Abraham Pharm D** Department of Pharmacy Practice, for their help and valuable ideas for the completion of this dissertation.

I owe a great deal to **Physicians, Postgraduate medical students, Nurses and all, including patients** without whose co-operation this dissertation would not have been possible.

I also express my thanks to **All the Teaching and Non Teaching Staffs** of Faculty of Pharmacy, PSG College of Pharmacy, Coimbatore, for their support and help.

I extend my sincere thanks to **My friends**, Especially to **Josin Mary Simon, Nikhil Vinod, Mannu Meria Wincent, Joyal Joy** for their unconditional support during the whole period of study.

I gratefully forward my affectionate thanks to my parents **Mr. Sandu.P.Issac, Mrs.Lizzy Sandu**, my brother **Asher Sandu** and **all my classmates** for their endless support, love and care, during my hurdles without which my work would be meaningless.

I extend my sense of gratitude to one and all who directly or indirectly have lent their helping hand in this venture.

*DEDICATED TO
THE GOD ALMIGHTY
PARENTS
GUIDE
&
OUR PROFESSION*

Abbreviations

ABBREVIATIONS

| | |
|------------------|---|
| COPD | Chronic obstructive pulmonary disease |
| FEV ₁ | Forced Expiratory Volume in 1 second |
| FVC | Forced Vital Capacity |
| GINA | Global Initiative for Asthma |
| GOLD | Global Initiative for Chronic Lung Diseases |
| MDI | Metered Dose Inhalers |
| NAC | National Asthma Council Australia |
| DPI | Dry Powder Inhalers |
| PEFR | Peak Expiratory Flow Rate |
| pMDI | pressured metered dose inhaler |
| ADMIT | Aerosol Drug Management Improvement Team |
| BAI | Breath Actuated Inhaler |
| HCP | Health Care Professionals |

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Abstract

ABSTRACT

Aim:

To compare the impact of various methods of counseling about inhalers in asthma and COPD patient and measure the effectiveness of counseling.

Methods:

A randomized , prospective and intervention study which classified 120 adults into three groups namely verbal group, Teach-Back group and Video Group. Inhaler technique and lung function was assessed using standardized checklists. Any error was recorded and frequent counseling was given to each group.

Results:

This study resulted that out of 120 patient's 66(55%) patients prefer to have Teach-Back method and 44(36.67%) patients prefer to have video demonstration and only 10(8.33%) people like to have verbal method. Also after giving all the three methods 77(64.17%) patients like to have combined method and 43(35.83%) patients like to have individual method of counseling.

Conclusion:

This study has shown that majority of the patients would like to have Teach-Back method as the preferable method of counseling rather than Video and Verbal methods. There by Teach-Back method will be the preferable method of inhaler education when comparing with the other two methods

KEY WORDS: asthma, COPD, inhalation techniques, inhaler device, counseling

Introduction

INTRODUCTION

Asthma and Chronic Obstructive Pulmonary Diseases (COPD) are among the most frequently occurring respiratory diseases and represent a major public health burden. They both are pulmonary diseases, resulting from interactions between environmental exposures and genetic predispositions incorrect technique when using inhaled medications frequently prevents patients from receiving the maximal benefit of their medications in Asthma and COPD. Recent studies confirm that:

- Regardless of the type of inhaler device prescribed, patients are unlikely to use inhalers correctly unless they receive clear instruction, including a physical demonstration
- The risk of misusing inhalers is particularly high in older and more debilitated patients
- Brief verbal instruction on correct technique, with a physical demonstration, is effective when repeated over time and can improve clinical outcomes.

Lung diseases like asthma and COPD are accompanied by a major burden of symptoms, health care utilization, lost of productivity and cost of medications on the individual and society. The mainstay of asthma and COPD treatment is by inhalation of medication to the site of disease process. The major advantage of inhalation therapy is that drugs are delivered directly into the airways, achieving higher local concentrations with significantly less risk of systemic side effects. The use of an inhaler device involves a complex series of steps, which need to be performed correctly. Failing to perform one or more steps correctly can substantially reduce delivery and hence effectiveness and safety of medication. It also leads to uncontrolled disease state, unwanted side effects, and can also cause higher treatment costs.⁽¹⁾

Asthma

Asthma is a heterogeneous disease, usually characterized by chronic airway inflammation. It is defined by the history of respiratory symptoms such as wheeze, shortness of breath, chest tightness and cough that vary overtime and in intensity, together with variable expiratory airflow limitation. [GINA 2014]

COPD

COPD is a common preventable and treatable disease, characterized by persistent airflow limitation that is usually progressive and associated with enhanced chronic inflammatory responses in the airways and the lung to noxious particles or gases. Exacerbations and co-morbidities contribute to the overall severity in individual patients. [GOLD 2014]

INHALATION THERAPY

An inhaler is a device which holds the drug that will be taken by breath in (inhaling). This allows the drug to deliver directly into the lungs where it is required which means that patients need smaller doses than the drug taken orally. This helps to decrease the incidence of side-effects. Inhalers are prescribed for patients with asthma or chronic obstructive pulmonary disease (COPD).

There are different types of inhaler devices available, including:

- Metered dose inhaler(MDI)
- Dry powder inhaler(DPI)

METERED DOSE INHALERS

The metered-dose inhaler (MDI) is an aerosol and currently one of the most common types of inhaler. The medication comes out of the inhaler as a mist or spray. A wide range of medications may be delivered by MDI: albuterol/salbutamol, beclomethasone, budesonide, fenoterol, fluticasone, ipratropium bromide, salmeterol, sodium cromoglycate, terbutaline. Some people may have difficulties activating the canister. An attachment is available for some inhalers, which makes activating the inhaler easier. Two types of MDI are:

Pressurized MDI: This type inhaler consists of a pressurized canister of medication and a mouthpiece. Pressing down on the inhaler releases a mist of medicine that breathe into the lungs. It contains chlorofluorocarbon propellants and surfactants. Some type of inhalers will be containing hydrofluoroalkane instead of chlorofluorocarbon.

Breath Activated MDI: It is an alternate kind of MDI that can be used by people who have a hard time mastering the technique of an MDI. Breath activated means that do not have to press on the canister to release the medicine. Instead, the medicine comes out automatically as breathe in.

DRY POWDER INHALERS

Dry powder inhaler device is used to deliver the contents of Rotacaps for the long-term treatment of chronic obstructive pulmonary disease (COPD) and asthma. These types of inhaler do not have a gas propellant to 'squirt' the medicine out of a canister. Instead, each dose contains a tiny amount of medicine in a powder form. Various devices are made by different companies. Each has a different method of providing the correct amount of powder for each dose. Some types are shown below.

Diskus: Diskus is a dry-powder inhaler that holds 60 doses. It features a built-in counter, so that you always know how many doses you have left in it.

Turbuhaler: Turbuhalers are a tube-shaped inhaler, which has the medication inside in the form of a dry powder. They have a removable cover and a twisting base. The device is 'breathe activated' which means the dry powder medication is 'sucked' from the device rather than 'fired' like it is from other devices. A Turbuhaler is a dry-powder inhaler available in an easy-to-use format. Some Turbuhalers feature a dose counter that shows the exact amount of medication left. If your Turbuhaler doesn't have a dose counter, then check for a red indicator in the windows on the side of the device. When you see red in the window, there are approximately 20 doses left and it's time to order a refill.

Rotahaler: Rotacaps, which can be obtained separately, contain a powder that can be inhaled, using the Rotahaler device. Rotacaps® are capsules of powdered medication which are placed in a Rotahaler. A Rotahaler is a plastic inhalation device which is breathe activated. This means when you inhale, the Rotahaler® releases medication from the Rotacap. When inhaled correctly, the medication has a better chance to reach the small airways. This increases the medication's effectiveness. Its portable size, efficiency and convenience make the Rotahaler® a desirable method for inhalation treatment.⁽²⁾

Inhalation therapy plays an important role in ASTHMA and COPD therapy. Studies have shown that the incorrect use of an inhaler diminishes the degree of therapeutic effect. Patient compliance usually refers to proper administration technique and also to the adherence to proper scheduling. There is adequate evidence that pharmacist conducted medication counseling significantly improves the compliance. Much of the morbidity from

asthma is believed to be due to factors such as denial of having a chronic condition, poor knowledge of the disease process and medication use, poor understanding on the use of inhalers and poor self-management⁽¹⁾. Poor inhaler technique is a major problem in managing asthma because the patient does not receive an optimal dose of the prescribed drug, resulting in reduced response to treatment and poor asthma control. Patients using inhalation therapies need careful instruction, including step-by-step demonstration and observation of their technique when dispensing the medication. Pharmacists are available not just when patients obtain their first inhaler, but also when they obtain refill inhalers, giving pharmacists the ideal opportunity to assess and educate their patients on an ongoing basis regarding correct inhaler technique.⁽³⁾ Patients who have a different primary language than the healthcare provider or who have low literacy skills present special challenges. Literacy is not a problem limited to patients for whom English is a second language. Use of a video program assures a standard level of teaching and consistent core of information not subject to the varying abilities or opinions of different educators. Greater individual impact through visual presentations can be obtained than through traditional reading or lecture oriented methods of patient education. Each inhaler type has different ways so if it is not properly educated patients won't take it properly so the chance of disease cure is less. Management of chronic airway disease is 10% medication and 90% education. For optimization of disease management, patients are required to demonstrate correct inhaler technique both at the outside of treatment and as they continue to use their inhaler over time.⁽⁴⁾

Inadequate inhaler instruction and poor inhalation technique moderates the effectiveness of the medication and are a major cause of poor disease control. Incorrect technique has been reported in up to 94% of patients. Patient-related determinants like sex, age, educational level, emotional problem, severity of obstruction, and diagnosis have been associated with incorrect inhalation technique. The type of inhalator device is an important determinant of incorrect inhalation technique. certain studies have demonstrated that patient using a pressured metered-dose inhaler (pMDI) made significantly more mistakes than users of dry powder inhalers, whereas another study showed better inhalation technique through the use of pMDIs.⁽⁵⁾ There is increasing evidence that permanent education of patients helped in better control and more successful treatment of asthma mostly due to encouragement of efficient self-care in accomplishing the set management targets ⁽⁶⁾ The recent ADMIT

(Aerosol Drug Management Improvement Team) series discussed current knowledge of asthma management, its components, factors that may limit patients' ability to achieve optimal asthma outcomes and instruments to measure asthma control, and attempted to raise awareness that correct device use is crucial for successful treatment. Improper inhalation technique can lead to decreased efficacy through reduced deposition of medication in the lungs. In a study of medical interns, only 5% were found to be able to correctly use an MDI device. The potential economic advantages of improving inhalation technique are likely to be compelling. Poor inhaler technique leads either to worse asthma control than could otherwise be achieved, or to stepping up to higher doses or prescribing of additional therapies such as fixed dose combinations in patients who could manage well with inhaled steroid therapy alone. Hence there is tremendous potential for improved inhaler technique to lead to better asthma control and reduced prescription costs.⁽⁷⁾

Reasons for inhaler errors;

1. Check natural inhaler technique e if the patient tends to breathe in slowly use an MDI or fast and hard use a DPI
2. Keep device consistent e don't mix MDI and DPI inhalers
3. Check for usage errors e if the patient displays errors of actuation and inhalation use a breath actuated MDI (BAI) or a small particle formulation
4. Use training aids for encouraging slow inhalation with MDI devices.

In order to optimize disease management, patients are required to demonstrate correct inhaler technique, both at the outset of treatment and as they continue to use their inhaler over time. However, studies indicate that between 40 and 60% of people with asthma are non-adherent to their medication. Patient's beliefs about their condition and medications impact on their level of adherence to regular medication. Patients who believe using their inhaler is an important part of their asthma management demonstrate higher levels of correct inhaler use.⁽⁷⁾

Delivery of inhaler technique education involves two main processes: evaluation of the inhaler technique; and provision of feedback on erroneous steps. Specifically, this involves HCPs observing how the patient uses their inhaler and comparing this technique with an inhaler technique checklist. Depending on the ability of the patient to use the inhaler

correctly, the HCP provides specific feedback on how to rectify the errors. It has been found that the nature of this feedback has significant impact on its effectiveness. Feedback can be given qualitatively or quantitatively. Research shows that, when it comes to the optimal delivery of feedback, quantitative feedback should be used. Currently, the nature of feedback in evidence-based inhaler technique educational interventions is qualitative.⁽⁸⁾ Adherence to inhalation therapy is complex, influenced by multiple aspects, including patient factors (eg, sex, age, and co-morbidities), different types of therapy regimens (eg. Poly pharmacy, frequency of dosing, and type of inhaler devices), and the quality of communication between health care providers and patients.⁽⁹⁾ A large number of patients still experience a high level of morbidity. Much of the morbidity from asthma is believed to be due to factors such as denial of having a chronic condition, poor knowledge of the disease process and medication use, poor understanding on the use of inhalers and poor self-management⁽¹⁰⁾. The incorrect use of an inhaler diminishes the degree of therapeutic effect. Pulmonary function tests, such as specific airway resistance and forced expiratory volume in the first second, have been shown to significantly improve following correction of improper technique. Proper technique results in deeper drug penetration into the bronchial tree, which has been shown not only to increase broncho-dilation, but also to decrease the drug's rate of clearance.⁽¹¹⁾ The use of multimedia in patient education involves the utilization of sounds, images, animations and films to convey messages effectively to patients. A study on the effect of a computer based multimedia tutorial found that such tutorials were effective in educating patients on inhaler technique as compared to having no intervention at all. The group of users that was educated on inhaler techniques using multimedia (video) was found to have greater improvement (44%) than the group that was educated using leaflets (19%), especially in terms of breathing coordination and breathing-in time.⁽¹²⁾

Giraud and Roche found that of patients who exhibited poor inhaler technique, only 15% were aware of the deficiency. Pinto Pereira et al demonstrate that only 41% of participants were able to display correct MDI technique, yet 92% were confident that their inhaler technique was appropriate. Souza et al reported that although over 98% of the participants claimed to use proper inhaler technique, 94.2% performed at least one error using the inhaler.⁽¹³⁾ Written instructions about drug treatment improve compliance, but few doctors provide them. Probably rather more doctors give their patients leaflets or booklets,

but evaluation of such material is unusual, although a patient information booklets on management of minor illnesses reduced consultations as used as referral manual.⁽¹⁴⁾ The use of video-based educational tools has become increasingly common among health care practitioners as a strategy for improving patients understanding and recall of information related to their health status and self-care. As video becomes more pervasive, print-based materials may become a less popular choice for health-related educational tools. Empirical evidence from both basics and applied research conflicts regarding video's efficacy related to other types of media. Theories of learning science highlight why the choice between Print and video to promote comprehension and recall is not always obvious. Cognitive learning theories suggest that learners possess a limited amount of cognitive resources to apply towards encoding new concepts. The effective design of materials may decrease the amount of cognition that must be directed towards processing extraneous aspects like format, wording and presentation style these materials will free resources to process the central messages that such materials are attempting to convey. Regarding the choice of medium, print and video each have been theorized to have potential advantages and disadvantages for prioritizing resources to encode incoming content⁽¹⁵⁾.

Background

BACKGROUND

Chronic obstructive lung diseases like asthma and chronic obstructive pulmonary disease (COPD) are accompanied by a major burden of symptoms, health care utilization, lost of productivity and cost of medications on the individual and society. Although effective drugs and evidence-based guidelines have been developed, no major change in morbidity and mortality can be recognized and data indicate that asthma and COPD in most patients are not well controlled. One reason can be found in the inability of patients to use their inhaler devices correctly.

The mainstay of asthma and COPD treatment is by inhalation of medication to the site of the disease process. The major advantage of inhalation therapy is that drugs are delivered directly into the airways, achieving higher local concentrations with significantly less risk of systemic side effects. The deposition pattern of inhaled drug in the respiratory tract is determined by a complex interaction between the device, the aerosol formulation and the patient's inhalation technique. The use of an inhaler device involves a complex series of steps, which need to be performed correctly. Failing to perform one or more steps correctly can substantially reduce delivery and hence effectiveness, and safety of medications.

There is a need of studies to explore the effectiveness and frequency of patient education and consider interventions to improve inhalation technique .This study to compare the impact of various methods of counseling about inhalers to asthma and COPD patient and measure the effectiveness of counseling.

Literature Review

LITERATURE REVIEW

- 1) **Andrea Hamelin, et al., (2009)** conducted a study on **“Pharmacist- led intervention study to improve inhalation technique in asthma and COPD patients”** in Germany. In this study, a total of 757 patients with asthma or COPD were randomly selected by 55 community pharmacies. At baseline, patients were interviewed and their inhalation technique was assessed with a 21-items checklist. Any error made was recorded and, if necessary, patients were instructed in the proper use of their device. After 4-6 weeks, demonstration of inhalation technique was repeated in the community pharmacies and a pre-post comparison was performed. The study identified a total of 597 patients who made at least one mistake in performing the inhalation technique at baseline. This number dropped to 214 from the first to the second appointment.

- 2) **J. van der Palen, et al., (1997)** conducted a study on **“Evaluation of the long-term effectiveness of instruction modes for inhaling medicines”** in Netherlands to develop a self management program for outpatient adult patients (between February and June 1994). A total of 152 COPD patients were randomized into two groups: personal instruction and a control group. Inhalation technique was assessed by using inhaler specific checklists. Errors were corrected by verbal instructions and visual demonstrations and patients had to demonstrate their inhalation technique, until no errors were made anymore. The control group did not receive instructions. Up to 9 months later, the patient’s inhalation technique was checked again using the same inhaler specific checklist. The result of this study was a 7% increase in the mean percentage of essential checklist items performed correctly in patients who followed instructions.

- 3) **Iman A Basheti, Carol L Armour , Helen K Reddel, and Sinitha Z Bosnic-Anticevich, (2009)** conducted a study on **“long term maintenance of pharmacist’s inhaler technique demonstration skill”**. The aim of the subject is to assess the

effectiveness of a single educational intervention, followed by patient education training, in pharmacists retaining their inhaler technique skills. From this study they conclude that providing community pharmacists with effective patient education tools and encouraging their involvement in educating patients may contribute to pharmacists maintaining their competence in correct inhaler technique long term.

- 4) **Geert N. Rootmensen, Anton R.J van Keimpema, Henk M Jansen, and Rob J. de Haan**, (2010) conducted a study on **“predictors of incorrect inhalation technique in patients with asthma or COPD: a study using validated videotaped scoring method”**. The aim of the study was to determine the effect of patient characteristics and type of inhaler device on inhalation technique in patient with asthma or COPD. In this study they found out that overall 40% of the patients made at least one essential mistake in their inhalation technique. Patients who never received inhalation instruction and patients who used more than one inhaler device made significantly more errors.

- 5) **Marija Crncevik Urek, Neven Tudoric et.al.**,(2005) conducted a study on **“Effect of educational programs on asthma control and quality of life in adult asthma patients”**. The aim of the study was to investigate the effectiveness of different forms of medical education in improving the control of asthma, and quality of life. In this study 60 adult patients with moderate persistent asthma they tested the benefit of individual verbal instruction written information and integrated asthma classes. During a 12 week period all patients recorded their asthma symptoms, morning and evening peak expiratory flow rates and the use of rescue medications. The study conclude that among the tested educational interventions the asthma school caused the best improvement in quality of life while individual verbal instructions produced the best overall response in both parameters of the asthma control and quality of life.

- 6) **Mariam Toumas-Shehata, David Price, Iman Amin Basheti and Sinitha Bosonic-Anticevich**(2014) conducted a study on **“ Exploring the role of quantitative**

feedback in inhaler technique education: a cluster-randomized , two-arm, parallel-group, repeated-measures study”. The aim of the study was to explore the role of feedback in inhaler technique education and its impact on the inhaler technique of patient over time. This study concludes that both the educational interventions resulted in an increase in the proportion of patients with correct inhaler technique from 4% to 51% in group I and from 6% to 83% in group II. The magnitude of improvement was statistically significant higher for group II compared with group I.

- 7) **Masaya Takemura, Katsumi Mitsui, et.al.,(2011)** conducted a study on **“Relationship between repeated instruction on inhalation therapy , medication adherence, and health status in chronic obstructive pulmonary disease”**. The aim of the study was to identify the factors that contribute to adherence to inhalation therapy and to investigate the relationship among these factors, adherence, and quality of life in patients with COPD. This study includes 88 patients who were potential participants, 55(63%) responded with usable information .Thereby the significant relationship between repeated instructions for inhalation technique, adherence to inhalation therapy, and HRQL in COPD.
- 8) **Prabhakaran L,Lim G, Abisheganaden J, Chee C B V, Choo Y M(2006)** conducted a study on **“Impact of an asthma education programme on patient’s knowledge inhaler technique and compliance to treatment”**. The aim of the study was to assess the impact of an asthma education programme (AEP) on knowledge of asthma and medication, compliance to treatment and inhaler technique, emergency department visits and hospital readmissions. This study includes 67 patients who completed the two phase AEP, there was significant improvement in some knowledge aspects. Thereby this study demonstrates the effectiveness of an AEP in patients hospitalized for asthma exacerbations.

- 9) **Richard J Roberts, J. Daniel Robinson, Paul L.Doering, John J.Dallman, and Roy A.Steeves (1982)** conducted a study on **“a comparison of various types of patient instruction in the proper administration of metered inhalers”**. The aim of the study is to compare the effectiveness of the manufacturer’s patient instruction sheets, pharmacist counseling, and a combination of the two on improving administration technique. The study includes 42 patients using inhalers was observed. They are then divided into three groups each group consist of 24 patients. Comparison was made between the three groups. This study shows that pharmacist counseling can significantly improve the degree of patient compliance in the administration of metered inhalers.
- 10) **Teck Long king, Evelyn Kui Yee Kho, Yiek Hung Tiong, Siti Norhajariah Binti Julaihi (2015)** conducted a study on *“comparison of effectiveness and time-efficiency between multimedia and conventional counseling on metered-dose inhaler technique education”*. The aim of the study is to evaluate whether multimedia counseling using a touch screen computer is as effective and time-efficient as conventional counseling in promoting correct metered dose inhaler technique, with or without the valved holding chamber. This study concludes that multimedia counseling and conventional counseling significantly improved MDI technique. Both methods showed comparable short term effectiveness and time-efficiency in MDI technique education. Valved Holding Chamber was beneficial especially for MDI-users with hand- lung coordination problems.
- 11) **Samantha Axtell, Seena Haines, and Jamie Fairclough, (2016)** conducted a study on **“Effectiveness of Various Methods of Teaching Proper Inhaler Technique; The Importance of Pharmacist Counseling”**. The aim of the study was to compare the effectiveness of four different instructional interventions in training proper inhaler technique. The result of the study was direct instruction of inhaler technique by a pharmacist was shown to be significantly more effective at enabling subjects to

demonstrate competence of all 7 critical steps of technique than either professionally produced multimedia videos or manufactured prepared instructional pamphlets.

- 12) **Douglas Jenkinson, Jan Davison, Sue Jones, Patricia Hawtin(1988)** conducted a study on **“Comparison of effects of a self management booklet and audiocassette for patients with Asthma”**. The aim of the study was to find out the effects of self management of asthma of a specially prepared book and audiocassette tape with similar contents. The study results that knowledge about the use of drugs was significantly increased in the groups who received

- 13) **Elizabeth A.H. Wilson, Densie C. Park et al.,(2010)** conducted a study on **“Media and memory; The efficacy of video and print materials for promoting patient education about asthma”**. The aim of the study was to examine the effects of presentation medium on immediate and delayed recall of information and assessed the effect of giving patients take-home materials after initial presentation. From the study they conclude that simple educational interventions can dramatically improve patient’s understanding and recall information about chronic health conditions. Patients in all of the intervention groups performed significantly better than control participants, suggesting that short, simple interventions can promote knowledge gain that can be sustained over extended time periods.

- 14) **Mohammed Saji S, Alhas Ja Jiju K, Siraj Sundaran(2012)** conducted a study on **“Study of Impact of Patient Counselling on the Quality of Life and Pulmory Function of Asthmatic Patient”**. The aim of the study was to assess the impact of counseling on quality of life and pulmonary function of asthmatics at a respiratory clinic and community pharmacy. The study findings were 28 patients were counseled and 25 in control group counseled group showed clinical improvement in total quality of life score from 30th day and high clinical improvement on the 90th day. No clinical improvement in total score of the control was observed.

- 15) Archana Arumugom, Venkatesh Chandrasekaran(2017) conducted a study on “**A Randomized Comparison Between Video Demonstration And Verbal Instruction in Improving Rota-Haler Technique in Children with Persistent Asthma: A Pilot Study**”. The aim of the study was to compare the technique of Rota-Haler use in children with persistent asthma immediately after receiving other verbal instruction or a video based demonstration and again at one month following intervention. This study concludes that Video demonstration is effective in improving the technique of Rota-Haler use at immediate assessment and at one month post intervention.

Aim & Objectives

AIM:

To compare the impact of various methods of counseling about inhalers to asthma and COPD patient and measure the effectiveness of counseling

OBJECTIVES:

Primary Objectives:

To assess the impact of various methods of counseling.

Secondary Objectives:

To assess the disease progression of the patient.

To assess the inhaler knowledge

Plan of Study

PLAN OF STUDY

PHASE I

- Literature Collection
- Generate potential Topics
- Selection of Title

PHASE II

- Literature Review
- Study Design
- Determine methodology for study

PHASE III

- Data Collection
- Follow up and Review
- Analysis of data

PHASE IV

- Statistical Analysis
- Result
- Conclusion

Methodology

METHODOLOGY:

The study protocol is submitted to institutional human ethics committee (IHEC, PSGIMSR) of the hospital for approval

Study Type : Randomized, prospective, intervention study.

Study Site : PSG Hospitals, Department of Pulmonology.

Study Duration : April 2017 to September 2017

STUDY POPULATION:

The study has to carried out in both male and female patients who are above the age of 18 who are using inhalers and Rota halers in their medication with or without spacer

INCLUSION CRITERIA:

- Male and Female patients with age more than 18 years of age.
- Patients attending Pulmonology outpatient department of PSG Hospitals, diagnosed with asthma/COPD and prescribed with an inhaler device on a daily basis
- Patients who are consenting to participate

EXCLUSION CRITERIA:

- Patients had changed to another inhalation medication like nebulization
- Patients who do not show up for their follow up

STATISTICAL ANALYSIS:

Analysis of study data is performed using Statistical Package for Social Sciences (SPSS). Student 't' test is performed to assess the improvement in inhalation technique, clinical outcome (based on FEV1 and PEF values), and relief of clinical symptoms based on questionnaire, at the baseline and at the last visit for patients in all the groups groups. A p value of ≤ 0.05 is considered to be statistically significant in student 't' test .



Results

RESULTS

The study was conducted with a total number of 120 patients and data specific to these patients were obtained.

DEMOGRAPHIC DETAILS OF THE STUDY POPULATION

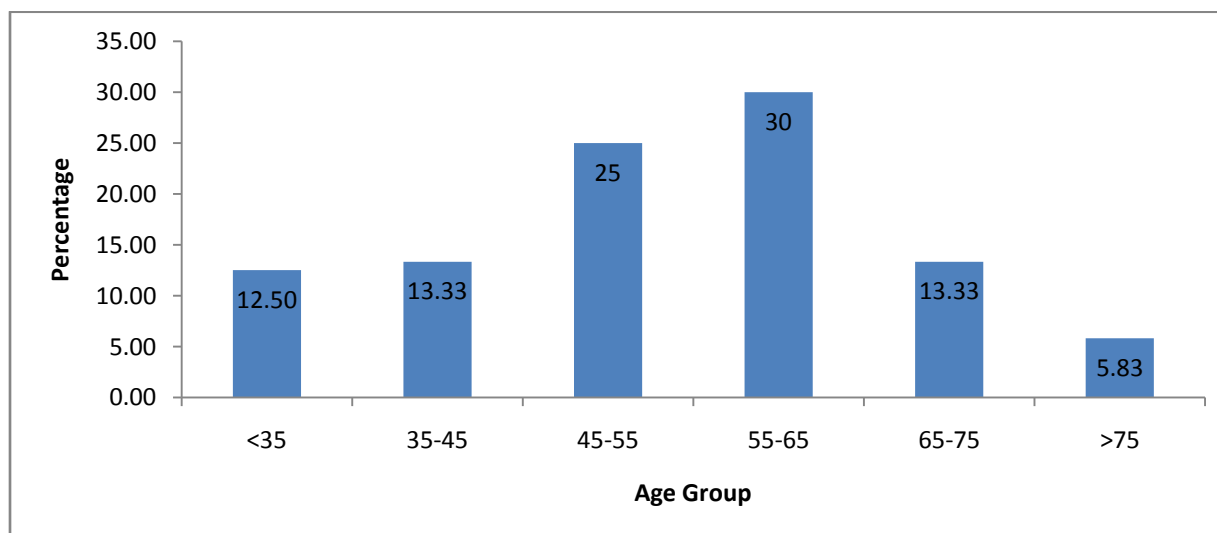
AGE WISE DISTRIBUTION:

The patients were grouped into various categories based on their age. 37 patients (30%) fell in the age group of 55- 65 years, followed by a number of 30 (25%) in the age group 45--55 years. The other values being 16(13.33%) in the age group 35– 45 years, 15 (12.5%) in the groups 65– 75 years and < 35 years of age, as shown in the table 1 and fig 1.

TABLE -1: Frequency Distribution of Age

| Age (in years) | Number of patients (n=120) | Percentage (%) |
|----------------|----------------------------|----------------|
| <35 | 15 | 12.50 |
| 35- 45 | 16 | 13.33 |
| 45- 55 | 30 | 25 |
| 55- 65 | 37 | 30 |
| 65- 75 | 16 | 13.33 |
| ≥75 | 7 | 5.83 |

FIGURE -1: Frequency Distribution of Age (n=120)

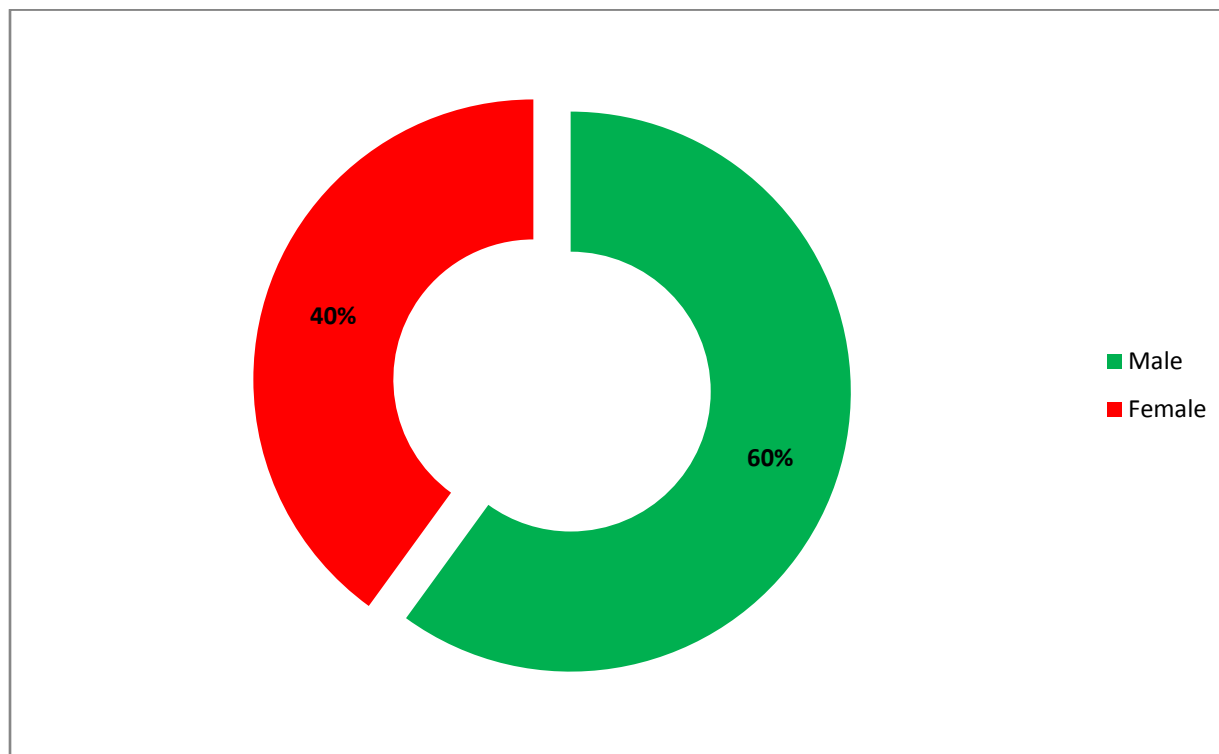


GENDER WISE DISTRIBUTION

Out of 120 patients, 72 (60%) were male and 48 (40%) were female, as shown in table 2 and fig 2

TABLE -2: FREQUENCY DISTRIBUTION OF GENDER

| GENDER | NO. OF PATIENTS (n=120) | PERCENTAGE (%) |
|---------------|------------------------------------|-----------------------|
| MALE | 72 | 60 |
| FEMALE | 48 | 40 |

FIG-2: FREQUENCY DISTRIBUTION OF GENDER (n=120)

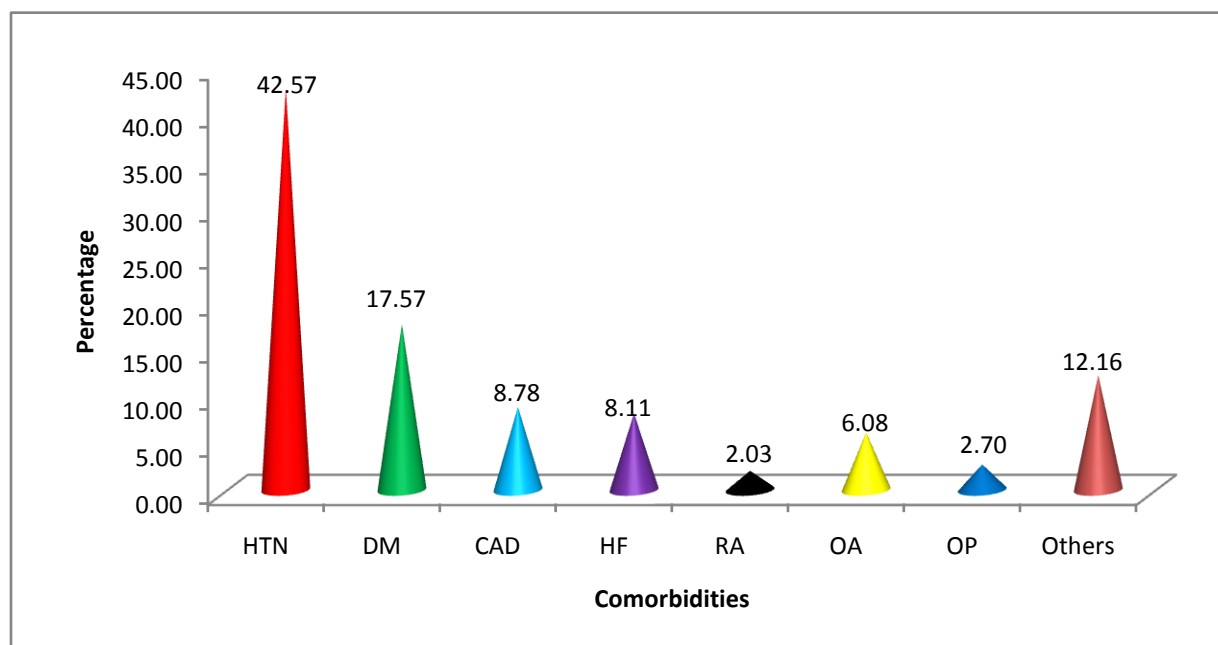
BASED ON CO- MORBIDITIES

Out of 120 patients, 52 (42.57%) had hypertension, 21 (17.57) had diabetes mellitus, 16.8% had cardiovascular disorders. Rheumatic arthritis, osteoarthritis and osteoporosis were found in numbers of 28 (2.03%), 20 (6.08) and 19 (2.70) patients respectively. Disease distribution in the study population is shown in table 3, fig 3.

TABLE-3: FREQUENCY DISTRIBUTION BASED ON CO- MORBIDITIES

| DISEASE CONDITION | NO. OF PATIENTS (n=120) | PERCENTAGE (%) |
|---------------------|----------------------------|----------------|
| Hypertension | 52 | 42.57 |
| Diabetes mellitus | 21 | 17.57 |
| CAD | 10 | 8.78 |
| HF | 11 | 8.11 |
| Osteoarthritis | 7 | 6.08 |
| Rheumatic arthritis | 2 | 2.03 |
| osteoporosis | 3 | 2.7 |
| others | 14 | 12.16 |

FIGURE-3: FREQUENCY DISTRIBUTION BASED ON CO-MORBIDITIES (n=120)



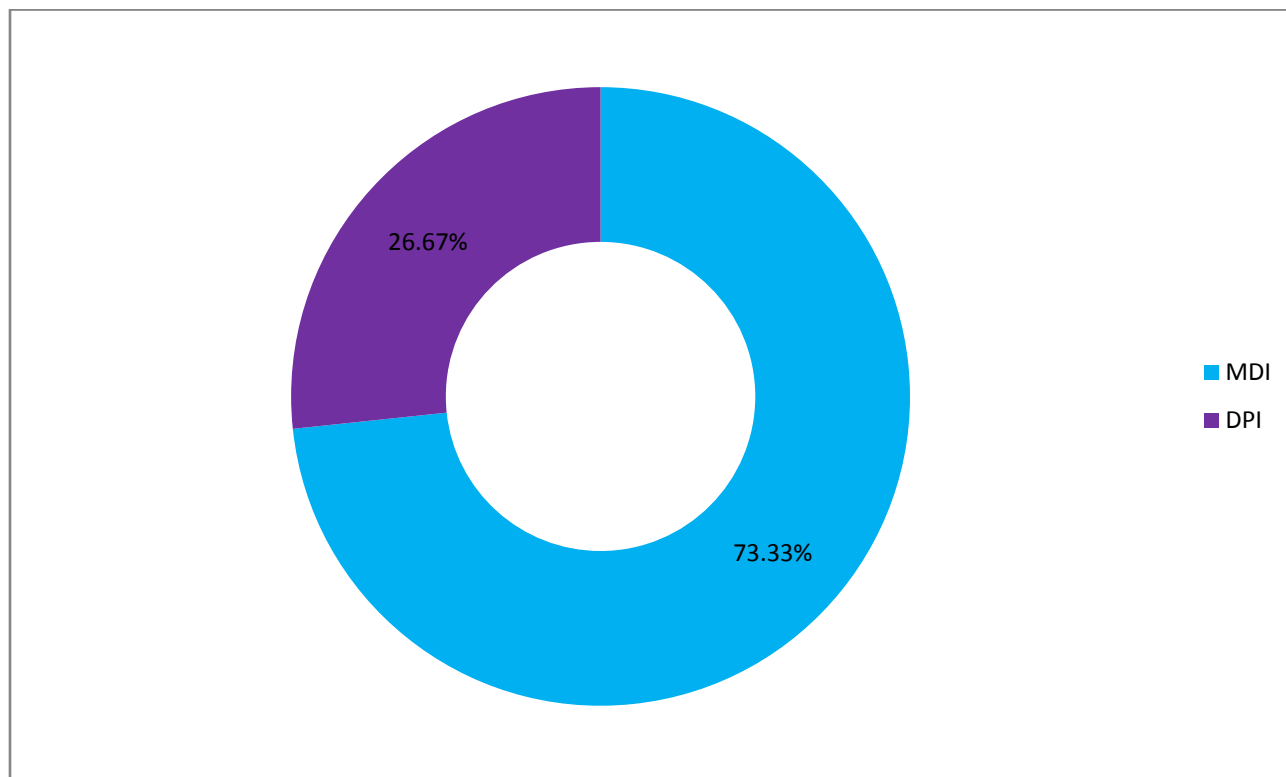
USAGE OF METERED DOSE INHALERS (MDI) AND DRY POWDER INHALERS (DPI)

Out of the 120 patients enrolled for the study, 73.33% were on MDI and the rest 26.6% were on DPI's .Percentage distribution of patients on MDI and DPI is displayed in figure 4 and the corresponding data is tabulated in table 4

TABLE-4: FREQUENCY DISTRIBUTION BASED ON INHALERS USED

| INHALER USED | NUMBER OF PATIENTS (n=120) | PERCENTAGE (%) |
|--------------|-------------------------------|----------------|
| MDI | 88 | 73.33 |
| DPI | 32 | 26.67 |

FIGURE-4: FREQUENCY DISTRIBUTION BASED ON INHALERS USED



ASTHMA CONTROL TEST

Asthma control test was performed in all the three groups of study population during the first and second review. Statistical analysis using anova showed that there is a significant change in asthma control test scores when first and second review is compared.

The p value was computed to be less than 0.005.

TABLE-5: STATISTICAL ANALYSIS OF ASTHMA CONTROL TEST

| | | Sum of Squares | Df | Mean Square | F | Sig. |
|---------------|----------------|----------------|----|-------------|--------|-------------|
| First review | Between Groups | 387.198 | 9 | 43.022 | 33.488 | .000 |
| | Within Groups | 86.075 | 67 | 1.285 | | |
| | Total | 473.273 | 76 | | | |
| Second review | Between Groups | 333.938 | 9 | 37.104 | 19.194 | .000 |
| | Within Groups | 129.516 | 67 | 1.933 | | |
| | Total | 463.455 | 76 | | | |

Mean value of asthma control test during the first test was computed to be 10.04 which increased to 16.181 during the second review. The improvement in ACT values was found to be statistically significant at $p < 0.000$.

MDI EVALUATION CHART

MDI evaluation chart was prepared and the patient knowledge on MDI was evaluated before (initial review) and after (second review) patient education. statistical analysis using paired t test was performed to check for the improvement in patient knowledge on MDI.

TABLE-6: ASSESSMENT OF PATIENT KNOWLEDGE ON MDI

| Study Population (n=120) | Mean | Std. Deviation | P- Value |
|-----------------------------|--------|----------------|---------------|
| Initial review | 1.8523 | 0.70368 | 0.000* |
| Final Review | 4.4432 | 0.58443 | |

The mean score value of patients during the first review was found to be 1.8523 and during the second review the value was increased to 4.4432. Paired t test showed a significance value lesser than 0.000, implicating a very significant improvement in patient knowledge on MDI.

MDI with spacer:

The patient knowledge on MDI with spacer was evaluated before (initial review) and after (final review) patient education. Statistical analysis using paired t test was performed to check for improvement in patient knowledge after intervention.

Table-7: ASSESSMENT OF PATIENT KNOWLEDGE ON MDI WITH SPACER

| Study Population (n=120) | Mean | Std. Deviation | P- Value |
|-----------------------------|--------|----------------|---------------|
| Initial review | 2.0588 | 0. 54723 | 0.000* |
| Final Review | 4.4118 | 0. 60891 | |

The mean score value of patients during the first review was found to be 2.0588 and during the final review the value was increased to 4.4118. Paired t test showed a significance value lesser than 0.000, implicating a very significant improvement in patient knowledge on MDI with spacer.

MDI without spacer:

Evaluation of the patient knowledge on MDI without spacer was also done before (initial review) and after (final review) patient education. Paired t test was performed to check for the improvement in patient knowledge.

Table-8: ASSESSMENT OF PATIENT KNOWLEDGE ON MDI WITHOUT- SPACER

| Study Population (n=120) | Mean | Std. Deviation | P- Value |
|-----------------------------|--------|----------------|---------------|
| Initial review | 1.7407 | 0. 75698 | 0.000* |
| Final Review | 4.4630 | 0. 57340 | |

The mean value of patients were found to be 1.7047 initially and increased to 4.4630 during final review. Paired t test showed a significant value lesser than 0.000 implicating a very significant improvement in patient knowledge on MDI without spacer.

DPI EVALUATION CHART.

Patients were given with DPIs and the patient knowledge on DPIs was evaluated before (initial review) and after (final review).paired t test was performed to check for the improvement in patient knowledge.

Table-9: ASSESSMENT OF PATIENT KNOWLEDGE ON DPI

| Study Population (n=120) | Mean | Std. Deviation | P- Value |
|-----------------------------|--------|----------------|---------------|
| Initial review | 4.4688 | 1.2696 | 0.000* |
| Final Review | 9.6250 | 0.6599 | |

PULMONARY FUNCTION TEST BASED ON FEC.

Pulmonary function test was performed to analyse the changes in FEC value, the baseline value was recorded and the FEC value after the second review was also recorded. Paired t test was performed to analyze the change in FEC value between the two groups.

TABLE-10: ASSESSMENT OF DISEASE PROGRESSION BASED ON FEC

| Study Population (n=120) | Mean | Std. Deviation | P- Value |
|-----------------------------|---------|----------------|---------------|
| FEC initial | 51.1628 | 9.94731 | 0.000* |
| FEC final | 57.5116 | 10.24549 | |

The baseline mean FEC value was found to be 51.162 and the mean FEC value after the second review was found to be 57.511. The significance value was estimated to be less than 0.005 implicating a significant improvement in the FEC value.

PULMONARY FUNCTION TEST BASED ON FEV1

Baseline FEV1 and FEV1 after second review were also recorded and compared using paired t test.

TABLE-11: ASSESSMENT OF DISEASE PROGRESSION BASED ON FEV1

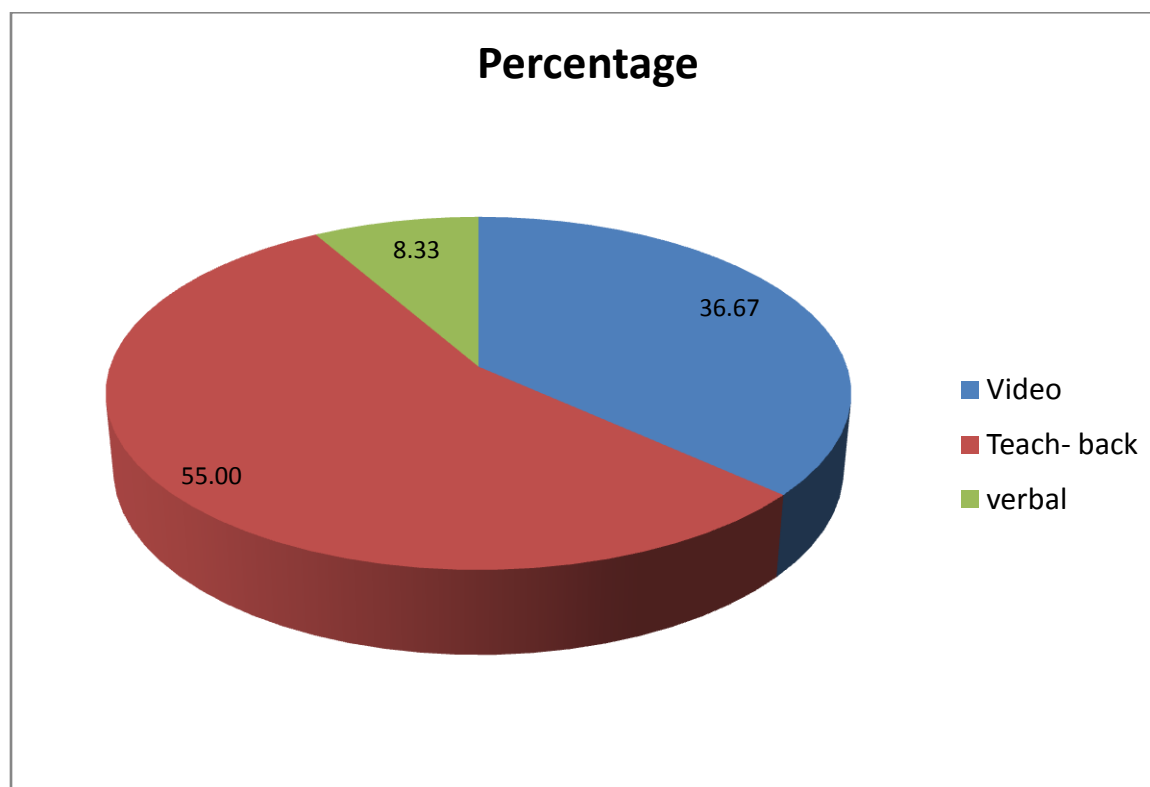
| Study Population (n=120) | Mean | Std. Deviation | P- Value |
|-----------------------------|---------|----------------|---------------|
| FEV1 initial | 40.3721 | 11.3368 | 0.000* |
| FEV1 final | 44.2326 | 10.7788 | |

The baseline mean FEV1 value was found to be 40.37 and the mean FEV1 value after the second review was found to be 44.23. The significance value was estimated to be less than 0.000 implicating a significant improvement in the FEC value.

COMPARISON OF VARIOUS METHODS OF COUNSELING.

TABLE-12: PERCENTAGE COMPARISON OF VARIOUS COUNSELING METHODS.

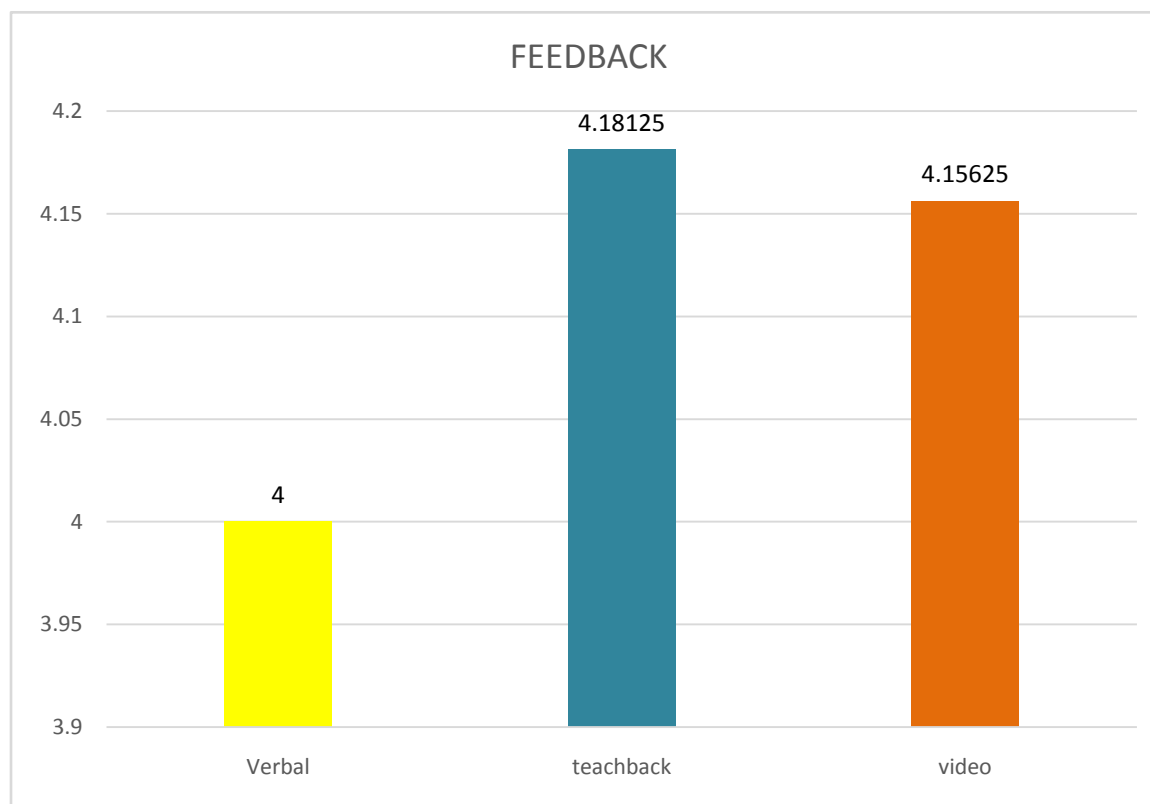
| Type of counseling | Number (n=120) | Percentage (%) |
|--------------------|----------------|----------------|
| Video | 44 | 36.67 |
| Teach- back | 66 | 55.00 |
| Verbal | 10 | 8.33 |

FIGURE-5: PERCENTAGE COMPARISON OF VARIOUS COUNSELING METHODS.

Based on data derived from feedback form, 55% of the study population was found to understand teach-back method, whereas 36% was found to understand video counseling. And the remaining population opted for verbal counseling.

Table-13: ASSESSMENT OF METHODS OF COUNSELING

| GROUP | N | Mean | Std. Deviation | P- Value |
|------------|-----|---------|----------------|----------|
| Verbal | 40 | 4 | 0.299572 | 0.042 |
| Teach-back | 40 | 4.18125 | 0.358001 | |
| Video | 40 | 4.15625 | 0.36989 | |
| Total | 120 | 4.1125 | 0.350345 | |

FIGURE-6: FREQUENCY DISTRIBUTION OF VARIOUS METHOD OF COUNSELING

Anova test was used to statistically compare various methods of educational interventions (verbal counseling, audio counseling and teach- back method) from the patient perspective. Data from the feedback form was utilized for the purpose.

The mean score given by the patients for teach- back method was marginally higher (4.18) when compared to video (4.15) and verbal counseling methods (4).

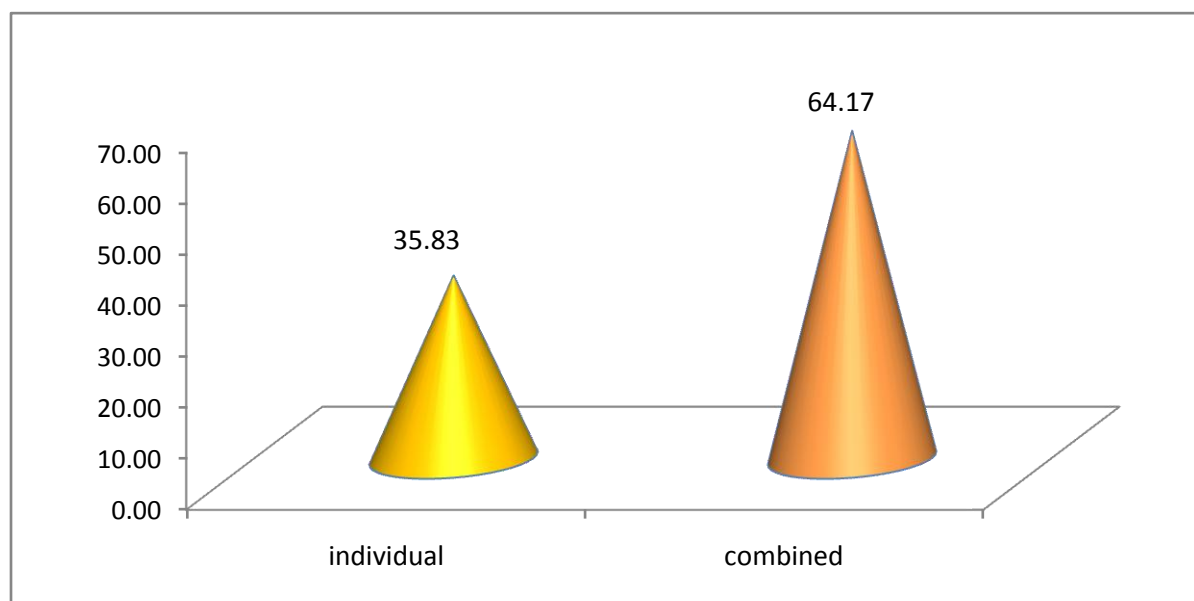
COMBINED METHODS Vs INDIVIDUAL METHOD:

Out of 120 patients 35.83% were interested in individual method of counseling while 64.17% preferred combined method.

Table-14: FREQUENCY DISTRIBUTION OF PATIENTS PREFERENCE TO METHODS

| Method | Number(n=120) | Percentage |
|------------|---------------|------------|
| Individual | 43 | 35.83 |
| Combined | 77 | 64.17 |

Fig-7: FREQUENCY DISTRIBUTION OF PATIENTS PREFERENCE TO METHODS



On enquiring whether the combined or individual modality is better, 65% of the study population considered combined modality to be better than counseling using a single aid.

Discussion

DISCUSSION

Asthma and chronic obstructive pulmonary disease (COPD) are among the most frequently occurring respiratory diseases and represent a major public health burden. They both are pulmonary diseases, resulting from interactions between environmental exposures and genetic predispositions incorrect technique when using inhaled medications frequently prevents patients from receiving the maximal benefit of their medications in Asthma and COPD.

This study aim is to compare the impact of various methods of counseling about inhalers to asthma and COPD patient and measure the effectiveness of counseling.

In this study participants are recruited based on inclusion and exclusion criteria. Collection of data is done and divided into three groups such as verbal, Teach-Back and Video. A total of 120 patients with asthma and COPD were included in this study. Patients were randomly selected with 40 patients in Verbal group, 40 patients in Teach-Back group and 40patients in Video group.

In this study participants were recruited based on inclusion and exclusion criteria. Collection of data was done using the data collection form. A total 120 patients were enrolled for the study. Study population had more of male participants (60%) and a large number of participants fell in the age group of 55- 65 and 45- 55 years.

In the study population, the most prevalent co- morbid condition was hypertension (43%) and diabetes (21%).

It was observed that 73.3% of the study population were on MDI and 26% was on DPI, showing that vast majority of asthma patients were prescribed with MDI.

Anova was utilized to find the changes in scores of Asthma Control Test. ACT Mean square difference between the group and within the group showed a significance value of <0.000 implicating that there is a significant improvement in ACT values between various groups after providing the educational intervention. The result suggests that verbal counseling, counseling by demonstration as well as combing both the techniques significantly improved patient inhaler usage technique.

MDI evaluation chart was prepared and was used for evaluating the knowledge on how to use MDIs. The score for MDI evaluation chart before and after educational intervention by taking into consideration the initial MDI evaluation score and the MDI score after second review respectively. Paired t test showed a significance value of <0.00 with a mean score value of 1.85 and 4.43 for the initial and final review respectively. Knowledge on MDI with spacers was also analysed. Paired t test showed that there is a significant improvement in the patient knowledge after the educational intervention ($p < 0.005$).

Knowledge was also evaluated in patients prescribed with MDI without spacer. Statistical analysis using paired t showed a significance improvement in knowledge at a p value < 0.005 .

Using DPI evaluation chart knowledge improvement of educational intervention was assessed by comparing the scores of initial and final review. The increase in mean score value was found to be statistically significant by using paired t test the p value less than 0.005.

These findings show that patient education on correct inhaler technique significantly improves patient knowledge and compliance. These findings are analogous to the study conducted by Teck Long King et al ⁽¹²⁾., wherein they demonstrated that simple instructions on correct inhaler usage can have significant impact on inhaler usage technique. Similar studies by Samantha Axtell et al ⁽¹³⁾., demonstrated that even a brief counseling of 2 minutes can significantly improve patient's MDI inhaler technique.

The improvement in disease progression was also analysed by taking pulmonary function test into consideration. Two parameters in PFT were considered, namely FEC and FEV₁. The mean improvement in FEC value was approximately by 6 points. Paired t test showed that the improvement is statistically very significant at $p < 0.000$. Similarly, mean value of FEV₁ in the initial review was found to be 40.37, The value was increased to 44.23 by second review. The improvement in mean scores was found to be statistically significant at $p < 0.005$.

Study conducted by Mohammed Saji S et al ⁽¹⁵⁾., also demonstrated a similar result showing significant improvement in FEC and FEV₁ values in counselled group of patients.

Almost all published reports on asthma related education agreed regarding improvement in at least some aspects of patient's health status. To quote a few are studies performed by Marija Crncevic Urek et al⁽⁶⁾, Leroyer C et al⁽¹⁷⁾ and Allen RM et al.⁽²¹⁾ Results show that patient administration techniques significantly improved after educational intervention.

Anova was used to find out the comparison of the methods used for educating patients from this study it reveals that Teach-Back method was found more effective than the Video method as well as the Verbal method. This study shows a slight variation in the effect of interventions in the study anova results that mean score value 4.18 value for teach-back and 4.15 for video and 4.0 for verbal on statistical analysis using anova the p value was computed to be 0.042. Thereby this study concludes that Teach-Back method was found better than the other two methods such as Verbal and Video.

Samantha Axtell et al⁽¹²⁾., shows that pharmacist intervention was compared against CDC video, YouTube video, pamphlet. They found that a brief 2 minute counseling session conducted by a pharmacist can significantly improve a patient's MDI inhaler technique. There is also evidence to suggest that the inhaler training provided in the study should be a repetitive ongoing process. Mariam Toumas-Shehata et al⁽⁷⁾., shows that there was significant improvement in qualitative and quantitative visual feedback on inhaler education rather than qualitative visual feedback. 83% of the participants are able to maintain the correct technique after 1 month that was significantly higher than that achieved by other research or interventions.

In this study about 55% of the participants are interested in Teach-Back method and 36.67% of the participants were interested in Video method and only a small population of 8.33% was interested in verbal method which includes the pamphlet.

On the second visit after giving all the counseling about 77 patients are interested in combined method where as only 43 participants are interested in individual method. About 64.17% participants would like to have all the three method of counseling and the rest 35.83% participants are interested in individual method.

Conclusion

CONCLUSION

Most of the asthma and COPD patients use their inhalers incorrectly. Thus education of the society is an important factor that may increase public awareness about medication and therefore improves patient compliance. Patients with asthma and COPD, on therapy with inhalation drugs, should be educated thoroughly on proper use of inhalers. Clinical pharmacists could play a pivotal role in improving health outcomes for patients with asthma and COPD by providing continuous education to the patients on how to use their inhaler devices properly, regularly checking the technique during follow up and encouraging patients' adherence to evidence-based management guidelines.

According to this study, there is the requirement of repetitive instruction to those patients who are using inhalers for Asthma and Chronic Obstructive Pulmonary Disease. The instruction is given to the patient in three different methods which includes verbal method which consist of pamphlets and the next one was Teach-Back in which the counselor will give information about using the inhaler and allow them to do it again and the final one was by the help of video demonstration in which the patient will be shown a video of to use the inhaler properly and this is then evaluated. With the help of a feedback form will find out which method was better. This study concludes that out of 120 patients 66(55%) patients prefer to have Teach-Back method and 44(36.67%) patients prefer to have video demonstration and only 10(8.33%) people like to have verbal method. Also after giving all the three methods 77(64.17%) patients like to have combined method and 43(35.83%) patients like to have individual method of counseling.

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Annexure 1



PSG Institute of Medical Sciences & Research

Institutional Human Ethics Committee

Recognized by The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)

POST BOX NO. 1674, PEELAMEDU, COIMBATORE 641 004, TAMIL NADU, INDIA

Phone : 91 422 - 2598822, 2570170, Fax : 91 422 - 2594400, Email : ihec@psgimsr.ac.in

To
Mr Shilz Sandu
II Year M Pharm
PSG College of Pharmacy
Coimbatore
Guide/s: Dr V Sivakumar / Dr RM PL Ramanathan

Ref: Project No.17/097

Date: March 31, 2017

Dear Mr Shilz Sandu,

Institutional Human Ethics Committee, PSG IMS&R reviewed and discussed your application dated 10.03.2017 to conduct the research study entitled "*Comparison of various methods of inhaler counseling in asthma and COPD patients*" during the IHEC meeting held on 24.03.2017.

The following documents were reviewed and approved:

1. Project submission form
2. Study protocol (Version 1 dated 10.03.2017)
3. Informed consent forms (Version 1 dated 10.03.2017)
4. Data collection tool (Version 1 dated 10.03.2017)
5. Permission letter from concerned Heads of Department
6. Current CVs of Principal investigator, Co-investigator
7. Budget

The following members of the Institutional Human Ethics Committee (IHEC) were present at the meeting held on 24.03.2017 at IHEC Secretariat, PSG IMS & R between 10.00 am and 11.00 am:

| Sl. No. | Name of the Member of IHEC | Qualification | Area of Expertise | Gender | Affiliation to the Institution Yes/No | Present at the meeting Yes/No |
|---------|---|---------------|---------------------------------------|--------|---------------------------------------|-------------------------------|
| 1 | Mr R Nandakumar (Chairperson, IHEC) | BA., BL | Legal Expert | Male | No | Yes |
| 2 | Dr. S. Bhuvaneshwari (Member-Secretary, IHEC) | MD | Clinical Pharmacology | Female | Yes | Yes |
| 3 | Dr S Shanthakumari | MD | Pathology, Ethicist | Female | Yes | Yes |
| 4 | Dr D Vijaya | M Sc., Ph D | Basic Medical Sciences (Biochemistry) | Female | Yes | Yes |

The study is approved in its presented form. The decision was arrived at through consensus. Neither PI nor any of proposed study team members were present during the decision making of the IHEC. The IHEC functions in accordance with the ICH-GCP/ICMR/Schedule Y guidelines. The approval is valid until one year from the date of sanction. You may make a written request for renewal / extension of the validity, along with the submission of status report as decided by the IHEC.



PSG Institute of Medical Sciences & Research

Institutional Human Ethics Committee

Recognized by The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)

POST BOX NO. 1674, PEELAMEDU, COIMBATORE 641 004, TAMIL NADU, INDIA

Phone : 91 422 - 2598822, 2570170, Fax : 91 422 - 2594400, Email : ihec@psgimsr.ac.in

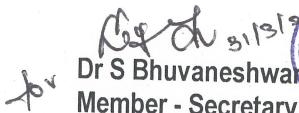
Following points must be noted:

1. IHEC should be informed of the date of initiation of the study
2. Status report of the study should be submitted to the IHEC every 12 months
3. PI and other investigators should co-operate fully with IHEC, who will monitor the trial from time to time
4. At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to a colleague after obtaining clearance from HOD, Status report, including accounts details should be submitted to IHEC and extramural sponsors
5. In case of any new information or any SAE, which could affect any study, must be informed to IHEC and sponsors. The PI should report SAEs occurred for IHEC approved studies within 7 days of the occurrence of the SAE. If the SAE is 'Death', the IHEC Secretariat will receive the SAE reporting form within 24 hours of the occurrence
6. In the event of any protocol amendments, IHEC must be informed and the amendments should be highlighted in clear terms as follows:
 - a. The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. Clause no. etc.)
 - b. Alteration in the budgetary status should be clearly indicated and the revised budget form should be submitted
 - c. If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval
 - d. If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented
 - e. If there are any amendments in the trial design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of the IHEC and only then can they be implemented
 - f. Any deviation-Violation/waiver in the protocol must be informed to the IHEC within the stipulated period for review
7. Final report along with summary of findings and presentations/publications if any on closure of the study should be submitted to IHEC

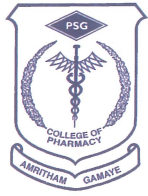
Kindly note this approval is subject to ratification in the forthcoming full board review meeting of the IHEC.

Thanking You,

Yours Sincerely,


Dr S Bhuvaneshwar
Member - Secretary
Institutional Human Ethics Committee





PSG COLLEGE OF PHARMACY

(An ISO 9001 : 2008 Certified Institution)

ACCREDITED WITH 'B' GRADE BY NAAC (1st CYCLE)

Affiliated to The Tamil Nadu Dr. M.G.R. Medical University, Chennai

Approved by Pharmacy Council of India and All India Council for Technical Education, New Delhi

Recognized as Industrial Scientific Research Organization by DSIR, Govt. of India, New Delhi

AVINASHI ROAD, PEELAMEDU, COIMBATORE 641 004, TAMILNADU, INDIA



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Website : www.psgpharma.ac.in

03/03/2017

To,

Dr. RM.PL RAMANTHAN (Prof & HOD)

Department of Pulmonology

PSG Hospitals, Coimbatore-04

Respected Sir,

This is to inform you that Shilz Sandu of M-Pharm II Year is doing a project on the title "COMPARISON OF VARIOUS METHODS OF INHALER COUNSELLING IN ASTHMA AND COPD PATIENTS", under the guidance of Dr. V. Sivakumar, Department of Pharmacy Practice, PSG College of Pharmacy, as the part of his curriculum as per The TamilnaduDr.MGR University Norms, thus I request you to kindly grant permission to collect the required data from your department.

Thanking you

Yours sincerely

Prudence A
3/3/17

Dr. Prudence A Rodrigues

Professor & Head

Department of Pharmacy Practice

PSG College of Pharmacy

Coimbatore 04.

Dr. RM. PL. Ramanathan
Dr. RM. PL. Ramanathan, M.D.M.
Prof & Head-Pulmonology & Critical Care Medicine,
PSG Super Speciality Hospital,
Coimbatore - 641 004.
Reg. No: 48899.

6/3/17

Annexure 2

Study Volunteer ID:
Study Volunteer Name:

PSG Institute of Medical Science and Research, Coimbatore
Institutional Human Ethics Committee
INFORMED CONSENT FORMAT FOR RESEARCH PROJECTS

I SHILZ SANDU, am carrying out a study on the topic: **COMPARISON OF VARIOUS METHODS OF INHALER COUNSELLING IN ASTHMA AND COPD PATIENTS** as part of my research project being carried out under the aegis of the Department of: PULMONOLOGY AND GENERAL MEDICINE

My research guide is: Dr. V. Sivakumar

The justification for this study is:

As most of the patients are suffering from ASTHMA and COPD and on inhalation therapy but most of them are not aware of the proper usage of the inhalers and their by the effectiveness of the therapy is not got by the patients so by the inhaler counselling effectiveness will be more and the disease will be in controlled.

There are many peoples in the society some are literate some are illiterate so by doing various methods of counselling and will be able to find out which one will be more beneficial for the patient and the disease progression will be there

The objectives of this study are:

Primary Objective:

To assess the impact of various methods of counselling

Secondary Objective:

- Assessment on disease progression of patient.
- Assessment of the inhaler knowledge.

Sample size: 120. (variable)

Study volunteers / participants are (specify population group & age group): The study has to carried out in both male and female patients who are above the age of 18 who are using inhalers in their medication with or without spacer

Location: PSG HOSPITAL PEELMEDU COIMBATORE

We request you to kindly cooperate with us in this study. We propose collect background information and other relevant details related to this study. We will be carrying out:

Initial interview (specify approximate duration): 10 minutes.

Data collected will be stored for a period of 5 years. We will / will not use the data as part of another study.

Health education sessions: Number of sessions: 2.

Study Volunteer ID:
Study Volunteer Name:

Approximate **duration** of each session: 5 minutes.

Clinical examination (Specify details and purpose): Not Applicable

Blood sample collection: Specify quantity of blood being drawn: 0 ml.

No. of times it will be collected: 0

Whether blood sample collection is part of routine procedure or for research (study) purpose:

1. Routine procedure 2. Research purpose

Specify **purpose**, discomfort likely to be felt and side effects, if any: _____

Whether blood sample collected will be stored after study period: Yes / No, it will be destroyed

Whether blood sample collected will be sold: Yes / No

Whether blood sample collected will be shared with persons from another institution: Yes / No

Medication given, if any, duration, side effects, purpose, benefits:

Whether medication given is part of routine procedure: Yes / No (If not, state reasons for giving this medication)

Whether alternatives are available for medication given: Yes / No (If not, state reasons for giving this particular medication)

Final interview (specify approximate duration): 10 mins. If **photograph** is taken, purpose:

Benefits from this study: The study will hopefully help to increase the adherence of the patient to the medications and there by the patient will be able to get much benefit from the therapy and thereby the treatment will be more effective.

Risks involved by participating in this study: NILL

How the **results** will be used: RESULTS WILL BE ANALYSED BY USING STUDENT T-TEST TO FIND OUT THE EFFECTIVENESS OF THE COUNSELLING AND THEREBY THE TREATMENT WILL BE MORE EFFECTIVE.

If you are uncomfortable in answering any of our questions during the course of the interview / biological sample collection, **you have the right to withdraw from the interview / study at anytime**. You have the freedom to withdraw from the study at any point of time. Kindly be assured that your refusal to participate or withdrawal at any stage, if you so decide, will not result in any form of compromise or discrimination in the services offered nor would it attract any penalty. You will continue to have access to the regular services offered to a patient. You will **NOT** be paid any remuneration for the time you spend with us for this interview / study. The information provided by you will be kept in strict confidence. Under no circumstances shall we reveal the identity of the respondent or their families to anyone. The information that we collect shall be used for approved research purposes only. You will be informed about any significant new findings - including adverse events, if any, – whether directly related to you or to other participants of this study, developed during the course of this research which may relate to your willingness to continue participation.

Study Volunteer ID:
Study Volunteer Name:

Consent: The above information regarding the study, has been read by me/ read to me, and has been explained to me by the investigator/s. Having understood the same, I hereby give my consent to them to interview me. I am affixing my signature / left thumb impression to indicate my consent and willingness to participate in this study (i.e., willingly abide by the project requirements).

Signature / Left thumb impression of the Study Volunteer / Legal Representative:

Signature of the Interviewer with date:

Witness:

Contact number of PI: 8281167195

Contact number of Ethics Committee Office: 0422 4345818

பூ சா கோ மருத்துவக் கல்லூரி மற்றும் ஆராய்ச்சி நிறுவனம்,

கோவை மனித நெறிமுறைக் குழு

ஒப்புதல் படிவம்

தேதி :

.....ஹில்ஸ் சன்டு.....ஆகிய நான், பூ சா கோ மருத்துவக் கல்லூரியின் / மருத்துவ மனையின் நுரையீரல் மற்றும் பொது மருத்துவம் துறையின் கீழ்,..... ஆஸ்துமா மற்றும் சி.ஓ.பி.டி நோயாளிகள் பயன்படுத்தும் இன்ஹேலரை பற்றிய ஆலோசனையின் பல்வேறு முறைகளின் ஒப்பீடு..... என்ற தலைப்பில் ஆய்வு மேற்கொள்ள 2ள்ளேன்.

என் ஆய்வு வழிகாட்டி என் ஆய்வு வழிகாட்டி (மாணவர்களுக்கு மட்டும்):
டாக்டர்.வி.சிவக்குமார்

ஆய்வு மேற்கொள்வதன் ஆய்வு மேற்கொள்வதன் அடிப்படை : ஆஸ்துமா மற்றும் சி.ஓ.பி.டி நோயாளிகள் இன்ஹேலஷன் சிகிச்சைக்கு ஆளாகுகின்றனர்.ஆனால் இன்ஹேலரை சரியாக பயன்படுத்துவதை அறியாமையால்,சிகிச்சை முழுபயன் அடைவதில்லை,ஆலோசனை திறனை அதிகரிப்பதால்,நோயை கட்டுப்படுத்தலாம்.இச்சமூகத்தில் கற்றவர்களும்,கல்லாதவர்களும் உண்டு.ஆகவே ஆலோசனையின் பல்வேறு முறைகளை ஒப்பிடுவதின் மூலம் சிறந்த முறையை தேர்ந்தெடுத்து பயனடைய செய்யலாம்.

ஆய்வின் நோக்கம்:

1. ஆலோசனையின் பல்வேறு முறைகளின் தாக்கத்தை மதிப்பீடு செய்ய.
2. நோய் வளர்ச்சியை மதிப்பீடு செய்ய.
3. இன்ஹேலரை குறித்துள்ள அறிவை மதிப்பீடு செய்ய.

ஆய்வில் பங்கு பெறும் நபர்களின் எண்ணிக்கை:120

ஆய்வில் பங்கு பெறுவோர் மற்றும் வயது: 18 வயதுக்கு மேற்பட்ட ஆண் மற்றும் பெண் நோயாளிகளில் இன்ஹேலரை பயன்படுத்துவார்களுள் இந்த ஆய்வு நடத்தப்படும்.

ஆய்வு மேற்கொள்ளும் இடம்: பூ.சா.கோ மருத்துவமனை,பீளமேடு,கோவை.

இந்த ஆய்வில் எங்களுடன் ஒத்துழைக்குமாறு கேட்டுக்கொள்கிறோம். நாங்கள் சில தகவல்களை இந்த ஆய்விற்காக சேகரிக்க 2ள்ளோம்.

ஆய்வு செய்யப்படும் முறை:

முதன்மை நோக்காணல்: 10 நிமிடங்கள்

இந்த ஆய்வில் கிடைக்கும் தகவல்கள் 5 வருடங்கள் பாதுகாக்கப்படும். இந்தத் தகவல்கள் வேறு ஆய்விற்குப் பயன்படுத்தப் படும் / பயன்படுத்தப் பட மாட்டாது.

சுகாதாரக் கல்வி:அமர்வுகள்:2 முறை ஒரு அமர்வுக்கான நேரம்:சுகாதாரக் கல்வி:10 நிமிடங்கள்

மருத்துவ பரிசோதனைகள்: **NIL ஒன்றுமில்லை**

இரத்த மாதிரி சேகரிப்பு: _____ மிலி _____ முறை

இரத்த மாதிரி எடுப்பது வழக்கமான சிகிச்சைக்காகவா அல்லது இந்த ஆய்விற்காகவா?

1. வழக்கமான சிகிச்சைக்காக
2. குறிப்பிட்ட ஆய்விற்காக

இதனால் ஏற்படக் கூடிய அசௌகரியங்கள் / பக்க விளைவுகள்:

இரத்த மாதிரிகள் ஆய்விற்குப் பின் பாதுகாத்து வைக்கப்படுமா?: ஆம் / இல்லை, அழிக்கப்படும்

சேகரிக்கப்பட்ட இரத்தம் விற்கப்படுமா?: ஆம் / இல்லை

சேகரிக்கப்பட்ட இரத்தம் வேறு நிறுவனத்துடன் பகிர்ந்து கொள்ளப்படுமா?: ஆம் / இல்லை

மருந்துகள் ஏதேனும் கொடுக்கப்படவிருந்தால் அவை பற்றிய விவரம் (கொடுக்கப்படும் காரணம், காலம், பக்க விளைவுகள், பயன்கள்):

மருந்துகள் கொடுக்கப்படுவது வழக்கமான சிகிச்சை முறையா? ஆம் / இல்லை (இல்லை என்றால் கொடுக்கப்படும் காரணம்)

கொடுக்கப்படும் மருந்துகளுக்கு மாற்று 2ள்ளதா?: ஆம் / இல்லை (ஆம் என்றால் இந்த குறிப்பிட்ட மருந்து கொடுக்கப்படும் காரணம்)

ஆய்வில் பங்கு பெறுவதால் ஏற்படும் பலன்கள்: இந்த ஆய்வு நோயாளிகளின் மருந்துகளை பின்பற்றுவதை அதிகரிக்க உதவும்,அதனால் சிகிச்சையின் பயன் அதிகரிக்கும்.

ஆய்வில் பங்கேற்பதால் ஏற்படும் அசௌகரியங்கள் / பக்க விளைவுகள்:

ஆய்வின் முடிவுகள் எந்த முறையில் பயன்படுத்தப் படும்? இந்த ஆய்வின் முடிவுகள் "ஸ்டூடன்ட் & டெஸ்ட்" மூலம் ஆய்வு செய்யப்படும்.இதன் மூலம் ஆலோசனையின் திறன் அதிகரிப்பதையும்,சிகிச்சையின் பயன் அதிகரிப்பதையும்,ஆய்வு செய்யலாம்.

இந்த ஆய்வின் கேள்விகளுக்கு பதிலளிப்பதிலோ, இரத்த மாதிரிகள் அல்லது திசு மாதிரிகள் எடுப்பதிலோ 2ங்களுக்கு ஏதேனும் அசௌகரியங்கள் இருந்தால், எந்த நேரத்தில் வேண்டுமானாலும் ஆய்விலிருந்து விலகிக்கொள்ளும் 2ரிமை 2ங்களுக்கு 2ண்டு. எப்பொழுது வேண்டுமானாலும் ஆய்விலிருந்து விலகும் 2ரிமை 2ங்களுக்கு 2ள்ளது. ஆய்விலிருந்து விலகிக்கொள்வதால் 2ங்களுக்கு அளிக்கப்படும் சிகிச்சை முறையில் எந்த வித பாதிப்பும் இருக்காது என்று 2ங்களுக்கு 2றுதியளிக்கிறோம். மருத்துவ மனையில் நோயாளிகளுக்கு அளிக்கப்படும் சேவைகளை நீங்கள் தொடர்ந்து பெறலாம். இந்த ஆய்வில் பங்கேற்க ஒப்புக்கொள்ளுவதால் வேறு எந்த விதமான கூடுதலான பலனும் 2ங்களுக்குக் கிடைக்காது. நீங்கள் அளிக்கும் தகவல்கள் இரகசியமாக வைக்கப்படும். ஆய்வில் பங்கேற்பவர்கள் பற்றியோ அவர்கள் குடும்பத்தைப் பற்றியோ எந்தத் தகவலும் எக்காரணம் கொண்டும் வெளியிடப்படாது என்று 2றுதியளிக்கிறோம். நீங்கள் அளிக்கும் தகவல்கள் / இரத்த மாதிரிகள் / திசு மாதிரிகள் அங்கீகரிக்கப்பட்ட ஆய்விற்கு மட்டுமே பயன்படுத்தப் படும். இந்த ஆய்வு நடைபெறும் காலத்தில் குறிப்பிடத்தகுந்த புதிய கண்டுபிடிப்புகள் அல்லது பக்க விளைவுகள் ஏதும் ஏற்பட்டால் 2ங்களுக்குத் தெரிவிக்கப்படும். இதனால் ஆய்வில் தொடர்ந்து பங்கு பெறுவது பற்றிய 2ங்கள் நிலைப்பாட்டை நீங்கள் தெரிவிக்க ஏதுவாகும்.

ஆய்வுக்குட்படுபவரின் ஒப்புதல்: இந்த ஆய்வைப் பற்றிய மேற்கூறிய தகவல்களை நான் படித்து அறிந்து கொண்டேன் / ஆய்வாளர் படிக்கக் கேட்டுத் தெரிந்து கொண்டேன். ஆய்வினைப் பற்றி நன்றாகப் புரிந்து கொண்டு இந்த ஆய்வில் பங்கு பெற ஒப்புக்கொள்கிறேன். இந்த ஆய்வில் பங்கேற்பதற்கான எனது ஒப்புதலை கீழே கையொப்பமிட்டு / கை ரேகை பதித்து நான் தெரிவித்துக் கொள்கிறேன்.

பங்கேற்பாளரின் பெயர், முகவரி :

பங்கேற்பாளரின் கையொப்பம் / கை ரேகை / சட்டபூர்வ பிரதிநிதியின் கையொப்பம் :

தேதி :

ஆய்வாளரின் கையொப்பம் :

தேதி :

ஆய்வாளரின் தொலைபேசி எண்:

மனித நெறிமுறைக் குழு அலுவலகத்தின் தொலைபேசி எண்: 0422 4345818

Annexure 3

PSG COLLEGE OF PHARMACY, Peelamedu, Coimbatore-641004

Department of pharmacy practice

| | | |
|----------------------------------|-------------|-------------------|
| Patient name: | Age: | Gender: M/F |
| Ip No: | Dept: | Con.No: |
| Smoking: | Occupation: | |
| DOA: | DOD: | Allergies if any: |
| Medical history: | | |
| LAB INVESTIGATIONS(if done any): | | |

INHALERS USING:

dry powder inhalers ☐ metered dose inhalers ☐

| BRAND NAME | GENERIC NAME | DOSE | FREQUENCY |
|------------|--------------|------|-----------|
| | | | |

Asthma Control Test (ACT) for people 12 year and older

Step 1: write the number in the score box provided

Step 2: add the score boxes for total

1. In the past 4 weeks how much of the time did your asthma keep you from getting as much done at work, school or at home?
 - 1) All of the time
 - 2) Most of the time
 - 3) Some of the time
 - 4) A little of the time
 - 5) None of the time
2. During the past 4 weeks, how often you had shortness of breath?
 - 1) More than a day
 - 2) Once a day
 - 3) 3 to 6 times a week
 - 4) Once or twice a week
 - 5) Not at all
3. During the past 4 weeks, how often did your asthma symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?
 - 1) 4 or more nights a week
 - 2) 2 or 3 nights a week
 - 3) Once a week
 - 4) Once or twice
 - 5) Not at all
4. During the past 4 weeks how often have you used your rescue inhaler or nebulizer medication (such as albuterol)
 - 1) 3 or more times per day
 - 2) 1 or 2 times per day
 - 3) 2 or 3 times per week
 - 4) Once a week or less
 - 5) Not at all
5. How would you rate your asthma control during the past 4 weeks?
 - 1) Not controlled at all
 - 2) Poorly controlled
 - 3) Somewhat controlled
 - 4) Well controlled
 - 5) Completely controlled

If the score is 19 or less then asthma may not be controlled as well as it could be

ஆஸ்துமா பரிசோதனை முறை - பன்னிரண்டு வயது உரியவர்களுக்கும் மற்றும் அதற்கு மேற்பட்டவர்களுக்கும்

- 1) உங்களுடைய எண்ணிக்கை ஒவ்வொரு பதிலுக்கும் கொடுக்கப்பட்டுள்ள மதிப்பெண் பெட்டியில் எழுதவும்
- 2) உங்களுடைய மதிப்பெண் பெட்டியில் உள்ள மதிப்பெண்ணின் மொத்த எண்ணிக்கையை எழுதவும்

1) கடந்த நான்கு வாரங்களில், எத்தனை முறை உங்களுடைய ஆஸ்துமா உங்களின் வேலைகளை (தொழில், பள்ள அல்லது வீடு) செய்ய விடாமல் தடுத்தது?

- 1) எல்லா நேரமும்
- 2) மிகப்பெரும்பாலான நேரம்
- 3) சில நேரம்
- 4) சிறிது நேரம்
- 5) ஒரு நேரமும் இல்லை

2) கடந்த நான்கு வாரங்களில், எத்தனை முறை உங்களுக்கு மூச்சுத்திணறல் இரைப்பு ஏற்பட்டுள்ளது?

- 1) ஒரு நாளுக்கு ஒரு முறை மேல்
- 2) ஒரு நாளுக்கு ஒரு முறை
- 3) மூன்று முதல் ஆறு முறை வாரத்திற்கு
- 4) ஒன்று அல்லது இரண்டு முறை வாரத்திற்கு
- 5) இல்லவேயில்லை

3) கடந்த நான்கு வாரங்களில், எத்தனை முறை உங்களுடைய ஆஸ்துமாவின் அறிகுறிகளால் (இருமல், நெஞ்சிருக்கம், நெஞ்சுவலி, இரைப்பு, இழப்பு) தூக்கம் கலைந்தது?

- 1) வாரத்தில் நான்கு அல்லது பல முறை இரவுகளில்
- 2) வாரத்தில் இரண்டு அல்லது மூன்று முறை இரவுகளில்
- 3) வாரத்தில் ஒரு முறை
- 4) ஒன்று அல்லது இரண்டு முறை
- 5) இல்லவேயில்லை

4) கடந்த நான்கு வாரங்களில், எத்தனை தடவை நீங்கள் மூச்சிழுப்பு மருந்து அல்லது தெளிகருவியை மருந்து உபயோகித்துள்ளீர்? (எ.டு. அல்பூட்டிரால்)

- 1) ஒரு நாளுக்கு மூன்று அல்லது பல முறைக்கு மேல்
- 2) ஒரு நாளுக்கு ஒன்று அல்லது இரண்டு முறைக்கு மேல்
- 3) வாரத்திற்கு இரண்டு அல்லது மூன்று முறைக்கு மேல்
- 4) வாரத்திற்கு ஒரு முறை அல்லது ஒன்றை விட குறைவு
- 5) இல்லவேயில்லை

5) கடந்த நான்கு வாரங்களில் உங்களுடைய ஆஸ்துமா கட்டுப்பாட்டை மதிப்பிடுக

- 1) கட்டுப்படவில்லை
- 2) மிக குறைவாக கட்டுப்படுத்தல்
- 3) ஓர் அளவிற்கு கட்டுப்படுத்தல்
- 4) நன்றாக கட்டுப்பட்டது
- 5) முழுமையாக கட்டுப்பட்டது

உங்களுடைய மதிப்பெண் 19 அல்லது குறைவாக இருந்தால், உங்களுடைய ஆஸ்துமா கட்டுப்படுத்துதல் கடினம்

Inhaler Device Assessment Tool - Form A1: MDI

Type of Inhalation device (Check one): ☐ MDI ☐ MDI plus spacer ☐ MDI plus spacer with mask

Instructions: Give one point for each step performed correctly (1=Yes, correct technique). Provide a reason for why a step was not done correctly for steps with a Score of 0.

When using this checklist as a teaching guide: For boxes with a score of 0, provide more teaching or coaching in these areas until a total score of 5 is obtained. Record the number of attempts until a satisfactory technique is obtained in the column "Coaching."

| Sequence of Critical Steps & Criteria | Score Circle 1 or 0 | | Coaching |
|--|------------------------|---|----------|
| 1 Removes cap. <i>Score 1 if:</i> <input checked="" type="checkbox"/> MDI: Removes cap from the mouthpiece. <input checked="" type="checkbox"/> MDI plus spacer: Removes cap(s), AND inserts canister into spacer correctly. <input checked="" type="checkbox"/> MDI plus spacer with mask: Removes cap(s), inserts canister mouthpiece into spacer. <i>Score 0 if:</i> <input type="checkbox"/> Forget to remove cap(s). <input type="checkbox"/> Metal canister of MDI not in plastic mouthpiece correctly. <input type="checkbox"/> Other: | 1 | 0 | |
| 2 Correctly primes device. <i>Score 1 if:</i> <input checked="" type="checkbox"/> MDI: Shakes the inhaler AND inhaler is upright <input checked="" type="checkbox"/> MDI plus spacer with mask: Shakes and delivers only 1 spray in the chamber, after on face with a good seal. <i>Score 0 if:</i> <input type="checkbox"/> Forget to shake. <input type="checkbox"/> Device held incorrectly (e.g., upside down). <input type="checkbox"/> Other: | 1 | 0 | |
| 3 Exhales. <i>Score 1 if:</i> <input checked="" type="checkbox"/> Exhales completely or breathes out to the end of a normal breath before putting apparatus to mouth. <input checked="" type="checkbox"/> MDI plus spacer: Hear a hissing sound. <input checked="" type="checkbox"/> MDI plus spacer with mask: Good fit of mask (nose and mouth covered). <i>Score 0 if:</i> <input type="checkbox"/> Does not exhale fully. <input type="checkbox"/> Other: | 1 | 0 | |
| 4 Inhales appropriately for device. <i>Score 1 if:</i> <input checked="" type="checkbox"/> MDI: Positioned 2-3 finger widths away from widely opened mouth. At the same time starts to breathe in slowly and depresses the inhaler to release 1 puff of medication. Continues breathing in slowly for about 5 seconds. Position with chin up. <input checked="" type="checkbox"/> MDI plus spacer: Puts the mouthpiece of spacer in the mouth, lips closed tightly around it, presses the inhaler. Breathes in slowly and deeply through the mouth for about 5 seconds. <input checked="" type="checkbox"/> MDI plus spacer with mask: Good seal over nose and mouth, press the inhaler, slow tidal breathing (that is, regular breathing in and out). <i>Score 0 if:</i> <input type="checkbox"/> Head not correctly positioned. <input type="checkbox"/> Block spray with teeth or tongue. <input type="checkbox"/> Blue or yellow Aerochamber: Hear a musical sound or whistling; breathing in too quickly. <input type="checkbox"/> Does not synchronize breathing in with puff (MDI alone). <input type="checkbox"/> Inhales through nose. <input type="checkbox"/> Delivering 2 sprays at once in the chamber for 1 inhalation. <input type="checkbox"/> Cough provoked by inhalation. <input type="checkbox"/> Other: | 1 | 0 | |
| 5 Holds breath. <i>Score 1 if:</i> <input checked="" type="checkbox"/> Person holds breath to count of 10 seconds. <input checked="" type="checkbox"/> Lips kept closed while holding breath. <input checked="" type="checkbox"/> MDI plus spacer with mask: No breath hold (see tidal breathing above) <input checked="" type="checkbox"/> Person waits 30-60 seconds before repeating process <i>Score 0 if:</i> <input type="checkbox"/> Holds breath for less than 10 seconds. <input type="checkbox"/> MDI plus spacer with mask: Holds breath in and out less than 6 times per dose of medication. (child <6 years) <input type="checkbox"/> Other: | 1 | 0 | |
| <div style="display: flex; justify-content: space-between;"> Date: _____ dd/mm/yyyy </div> | | | |
| TOTAL SCORE | | | |

Inhaler Device Assessment Tool - Form A2

Type of inhalation device: **MDI plus spacer**

Instructions Give one point for each step performed correctly (1=Yes, correct technique). Provide a reason for why a step was not done correctly for steps with a Score of 0.

When using this checklist as a teaching guide: For boxes with a score of 0, provide more teaching or coaching in these areas until a total score of 5 is obtained. Record the number of attempts until a satisfactory technique is obtained in the column "Coaching."

| Sequence of Critical Steps & Criteria | Score Circle 1 or 0 | | Coaching |
|--|------------------------|---|----------|
| 1 Removes cap. <i>Score 1 if:</i> <input checked="" type="checkbox"/> Removes cap, AND inserts canister into spacer correctly. <i>Score 0 if:</i> <input type="checkbox"/> Forgets to remove cap. <input type="checkbox"/> Metal canister of MDI not inserted correctly into plastic holder. <input type="checkbox"/> Forgets to monitor medication doses and MDI is empty. <input type="checkbox"/> Other: | 1 | 0 | |
| 2 Correctly primes device. <i>Score 1 if:</i> <input checked="" type="checkbox"/> Shakes the MDI upright with the spacer/mask. <i>Score 0 if:</i> <input type="checkbox"/> Forgets to shake. <input type="checkbox"/> Device held incorrectly (e.g., upside down). <input type="checkbox"/> Other: | 1 | 0 | |
| 3 Exhales. <i>Score 1 if:</i> <input checked="" type="checkbox"/> Exhales completely or breathes out to the end of a normal breath before putting the spacer to mouth <input checked="" type="checkbox"/> <u>For younger child (4-6 years):</u> With correct seal on mouthpiece may exhale into spacer. <i>Score 0 if:</i> <input type="checkbox"/> Forgets to exhale. <input type="checkbox"/> Does not exhale completely. <input type="checkbox"/> Other: | 1 | 0 | |
| 4 Inhales appropriately for device. <i>Score 1 if:</i> <input checked="" type="checkbox"/> Puts the mouthpiece of spacer in the mouth, lips closed tightly around it, depress MDI. <input checked="" type="checkbox"/> Breathes in slowly and deeply through the mouth for about 5 seconds. <input checked="" type="checkbox"/> <u>For younger child (4-6 years):</u> during exhalation depress the MDI and breathe in slowly and deeply through the mouth as able. <i>Score 0 if:</i> <input type="checkbox"/> Head not correctly positioned or with slouching posture. <input type="checkbox"/> Blocks spray with teeth or tongue. <input type="checkbox"/> Inhales through the nose. <input type="checkbox"/> Breathes in too quickly (hear a whistling or musical sound from spacer). <input type="checkbox"/> Delivers 2 sprays at once for 1 inhalation. <input type="checkbox"/> Other: | 1 | 0 | |
| 5 Holds breath. <i>Score 1 if:</i> <input checked="" type="checkbox"/> Holds breath to count of 10 seconds. <input checked="" type="checkbox"/> Lips are kept closed while holding breath. <input checked="" type="checkbox"/> Waits 30-60 seconds before repeating process <i>Score 0 if:</i> <input type="checkbox"/> Holds breath less than 10 seconds. <input type="checkbox"/> Does not wait 30-60 seconds between doses. <input type="checkbox"/> Other: | 1 | 0 | |

Date: _____

dd/mm/yyyy
TOTAL SCORE

ROTAHALER KNOWLEDGE ASSESSMENT

| <i>MEDICATION CHEKLIST</i> | <i>APPOINTMENT</i> | | <i>1ST VISIT</i> | | <i>2ND VISIT</i> | |
|---|---------------------------|------------------|------------------------------------|------------------|------------------------------------|------------------|
| | <i>YES</i> | <i>NO</i> | <i>YES</i> | <i>NO</i> | <i>YES</i> | <i>NO</i> |
| <ul style="list-style-type: none"> • Remove cap: • Insert the rotacap correctly: • Rotate the rotahaler: • Exhale: • Close the mouth: • Tilting head back ward: • Inhale and holding breath: • Avoid exhaling into device: • Wipe off moth peace:: • Rinse mouth after inhaler use: • Remove the rotacap and dispose • close the mouth piece: | | | | | | |

FEEDBACK FORM

| Verbal Method | Teach-Back Method | Video Method |
|---------------|-------------------|--------------|
|---------------|-------------------|--------------|

| Patient name | Inhaler type | Date |
|--------------|--------------|------|
| | | |

Your objective feedback would be greatly appreciated.

Please answer all the statements according to the following 1 to 5 scale:-

1= Strongly Disagree (SD), 2 = Disagree (D), 3 = Neutral (N), 4 = Agree (A) and
5 = Strongly Agree (SA)

Please **circle a number** between 1 and 5 to indicate which response best fits your experience of the presentation.

| | | SA | A | N | D | SD |
|--|---|----|---|---|---|----|
| | The information was well conveyed | 5 | 4 | 3 | 2 | 1 |
| | Are you confident enough in doing all the steps correctly | 5 | 4 | 3 | 2 | 1 |
| | The counselling was time consuming | 5 | 4 | 3 | 2 | 1 |
| | The counselling was helpful in clearing doubts | 5 | 4 | 3 | 2 | 1 |
| | Are you interested in further counselling | 5 | 4 | 3 | 2 | 1 |
| | | SA | A | N | D | SD |
| | Verbal Method | | | | | |
| | The leaflet was clear and easy to understand | 5 | 4 | 3 | 2 | 1 |
| | I feel comfortable and able to follow | 5 | 4 | 3 | 2 | 1 |
| | I feel complete confident in doing my inhaler | 5 | 4 | 3 | 2 | 1 |
| | I felt supported and encouraged | 5 | 4 | 3 | 2 | 1 |
| | Teach-Back Method | | | | | |
| | The educated method was easily understood | 5 | 4 | 3 | 2 | 1 |
| | I was comfortable with my ability to talk with the counsellor | 5 | 4 | 3 | 2 | 1 |
| | I feel complete confident in doing my inhaler | 5 | 4 | 3 | 2 | 1 |
| | I felt supported and encouraged | 5 | 4 | 3 | 2 | 1 |
| | Video Method | | | | | |
| | The content of video was clear and easy to understand | 5 | 4 | 3 | 2 | 1 |
| | I feel comfortable and able to follow | 5 | 4 | 3 | 2 | 1 |
| | I feel complete confident in doing my inhaler | 5 | 4 | 3 | 2 | 1 |
| | I felt supported and encouraged | 5 | 4 | 3 | 2 | 1 |

Please return your completed feedback form to counsellor.

Thank you.

கருத்து வடிவம்

| வாய்மொழி முறை | கற்பித்தல்-மீண்டும் முறை | வீடியோ முறை |
|---------------|--------------------------|-------------|
|---------------|--------------------------|-------------|

| நோயாளியின் பெயர் | இன்ஹேலர் வகை | தேதி |
|------------------|--------------|------|
| | | |

உங்கள் கருத்துகள் பெரிதும் பாராட்டப்படும்

பின் வரும் அறிக்கைகளுக்கு 1 முதல் 5 என்னும் எண்ணில் உங்கள் பதிலை பதிவு செய்யவும்

- 1 = கடுமையான கருத்து வேறுபாடு (SD)
 2 = கருத்து வேறுபாடு (D)
 3 = நடுநிலை (N)
 4 = ஏற்கிறேன் (A)
 5 = வலிமையாக ஏற்கிறேன் (SA)

உங்கள் அனுபவத்திற்கு ஏற்ப பதில்களை 1 மற்றும் 5 இடையே உள்ள ஒரு எண்ணை வட்டமிட்டு கொள்ளவும்.

| | SA | A | N | D | SD |
|--|----|---|---|---|----|
| தகவல்கள் நன்கு தெரிவிக்கப்பட்டது | 5 | 4 | 3 | 2 | 1 |
| அனைத்து படிகளையும் சரியாக செய்வீர்கள் என்ற நம்பிக்கை உள்ளதா? | 5 | 4 | 3 | 2 | 1 |
| ஆலோசனை நீண்ட நேரம் நடைபெற்றது | 5 | 4 | 3 | 2 | 1 |
| ஆலோசனை உங்கள் சந்தேகங்களை புரிந்துகொள்ள உதவியாக இருந்தது | 5 | 4 | 3 | 2 | 1 |
| மேலும் ஆலோசனையை நீட்ட விரும்புகிறீர்களா? | 5 | 4 | 3 | 2 | 1 |
| | SA | A | N | D | SD |

| | வாய்மொழி முறை | | | | | |
|--|--|---|---|---|---|---|
| | துண்டுபிசுரம் தெளிவாக மற்றும் புரிந்து கொள்ள எளிதாக இருந்தது | 5 | 4 | 3 | 2 | 1 |
| | எனக்கு வசதியாகவும் பின்பற்ற எளிதாகவும் இருந்தது | 5 | 4 | 3 | 2 | 1 |
| | என் இன்ஹேலரை சரியாக பயன்படுத்துவேன் என்ற முழு நம்பிக்கை எனக்கு உண்டு | 5 | 4 | 3 | 2 | 1 |
| | எனக்கு ஆதரவும் ஊக்கமும் கிடைத்தது | 5 | 4 | 3 | 2 | 1 |

| | | | | | | |
|--|---|---|---|---|---|---|
| | கற்பித்தல்-மீண்டும் முறை கற்பித்த முறை எளிதாக புரிந்து கொள்ளப்பட்டது ஆலோசகரிடம் பேச வசதியாக இருந்தது | 5 | 4 | 3 | 2 | 1 |
| | என் இன்ஹேலரை சரியாக பயன்படுத்துவேன் என்ற முழு நம்பிக்கை எனக்கு உண்டு | 5 | 4 | 3 | 2 | 1 |
| | எனக்கு ஆதரவும் ஊக்கமும் கிடைத்தது | 5 | 4 | 3 | 2 | 1 |

| | | | | | | |
|--|--|---|---|---|---|---|
| | வீடியோ முறை வீடியோவின் உள்ளடக்கத்தை தெளிவாக புரிந்துகொள்ள முடிந்தது | 5 | 4 | 3 | 2 | 1 |
| | எனக்கு வசதியாகவும் பின்பற்ற எளிதாகவும் இருந்தது | 5 | 4 | 3 | 2 | 1 |
| | என் என் இன்ஹேலரை சரியாக பயன்படுத்துவேன் என்ற முழு நம்பிக்கை எனக்கு உண்டு | 5 | 4 | 3 | 2 | 1 |
| | எனக்கு ஆதரவும் ஊக்கமும் கிடைத்தது | 5 | 4 | 3 | 2 | 1 |

ஆலோசகரிடம் உங்கள் கருத்து வடிவத்தை கொடுக்கவும்

நன்றி

FEEDBACK FORM

| | | |
|----------------------|--------------------------|---------------------|
| Verbal Method | Teach-Back Method | Video Method |
|----------------------|--------------------------|---------------------|

| Patient name | Inhaler type | Date |
|--------------|--------------|------|
| | | |

Your objective feedback would be greatly appreciated.

Please answer all the statements according to the following 1 to 5 scale:-

1 = Strongly Disagree (SD), 2 = Disagree (D), 3 = Neutral (N), 4 = Agree (A) and 5 = Strongly Agree (SA)

Please **circle a number** between 1 and 5 to indicate which response best fits your experience of the presentation.

| | | SA | A | N | D | SD |
|--|---|----|---|---|---|----|
| | The information was well conveyed | 5 | 4 | 3 | 2 | 1 |
| | Are you confident enough in doing all the steps correctly | 5 | 4 | 3 | 2 | 1 |
| | The counselling was time consuming | 5 | 4 | 3 | 2 | 1 |
| | The counselling was helpful in clearing doubts | 5 | 4 | 3 | 2 | 1 |
| | Are you interested in further counselling | 5 | 4 | 3 | 2 | 1 |

➤ Which method was easy to understand?

➤ Out of three which method you prefer to have?

➤ Which one you feel better, either individual or combined method?

Please return your completed feedback form to counsellor.

Thank you.

கருத்துவடிவம்

| வாய்மொழி முறை | கற்பித்தல்-மீண்டும் முறை | வீடியோ முறை |
|---------------|--------------------------|-------------|
| | | |

| நோயாளியின் பெயர் | இன்டேலர் வகை | தேதி |
|------------------|--------------|------|
| | | |

உங்கள் கருத்துகள் பெரிதும் பாராட்டப்படும்

பின்வரும் அறிக்கைகளுக்கு 1 முதல் 5 என்னும் எண்ணில் உங்கள் பதிலை பதிவு செய்யவும்

1 = கடுமையான கருத்துவேறுபாடு (SD) 4 = கருத்து வேறுபாடு (D)
3 = நடுநிலை (N) 2 = ஏற்கிறேன் (A) 5 = வலிமையாக ஏற்கிறேன் (SA)

உங்கள் அனுபவத்திற்கு ஏற்ப பதில்களை 1 மற்றும் 5 இடையே உள்ள ஒரு எண்ணை வட்டமிட்டு கொள்ளவும்.

| | SA | A | N | D | SD |
|--|----|---|---|---|----|
| தகவல்கள் நன்கு தெரிவிக்கப்பட்டது | 5 | 4 | 3 | 2 | 1 |
| அனைத்து படிகளையும் சரியாக செய்வீர்கள் என்ற நம்பிக்கை உள்ளதா? | 5 | 4 | 3 | 2 | 1 |
| ஆலோசனை நீண்ட நேரம் நடைபெற்றது | 5 | 4 | 3 | 2 | 1 |
| ஆலோசனை உங்கள் சந்தேகங்களை புரிந்துகொள்ள உதவியாக இருந்தது | 5 | 4 | 3 | 2 | 1 |
| மேலும் ஆலோசனையை நீட்ட விரும்புகிறீர்களா? | 5 | 4 | 3 | 2 | 1 |

எந்த முறை புரிந்து கொள்ள எளிதாக இருந்தது?

எந்த முறையை பின்பற்ற விரும்புகிறீர்கள்?

எந்த முறையை வரும்புகிறீர்கள்? தனிப்பட்ட முறையா அல்லது ஒருங்கிணைந்த முறையா?

ஆலோசகரிடம் உங்கள் கருத்து வடிவத்தை கொடுக்கவும்

நன்றி

HOW TO USE INHALERS PROPERLY?

STEP I:

Shake the inhaler well before use (3-4 shakes)



STEP II:

Remove the cap from your inhaler



STEP III:

Breathe out completely



STEP IV:

Stand straight and tilt head backwards



STEP V:

Put the mouthpiece **between your teeth** and close your lips



STEP VI:

Press the top and inhale slowly



STEP VII:

Hold the breath for 10 seconds and slowly exhale



Always keep in mind:

- Stand straight or sit upright
- Tilt your head back slightly while taking inhaler
- Never let anyone else use your inhaler.
- Keep your spacer away from heat sources.
- Wash your mouth after inhalation
- If your symptoms do not improve or if they become worse, check with your doctor.

இன்ஹேலரை எப்படி சரியாக பயன்படுத்துவது?

படி I:

பயன்படுத்துவதன் முன்பு இன்ஹேலரை நன்கு குலுக்கவும். (3-4 குலுக்கு)



படி II:

இன்ஹேலரின் தொப்பியை நீக்கவும்.



படி III:

மூச்சை முற்றிலும் வெளியேற்றவும்.



படி IV:

நேராக நின்று, தலையை சிறிதாக சாய்கவும்.



படி V:

உங்களின் பற்களை இடையே ஊதுகுழலை வைத்து உதடுகளை மூடவும்.



படி VI:

இன்ஹேலரின் மேற்பகுதியை அழுத்தி மெதுவாக மூச்சை இழுக்கவும்.



படி VII:

10 விநாடிகளுக்கு மூச்சை பிடித்துவைத்து, பின் மெதுவாக வெளியேற்றவும்.



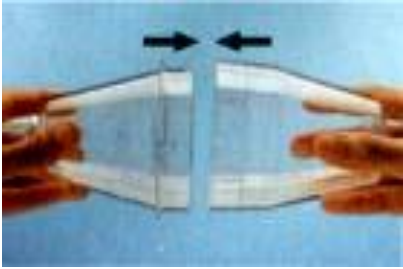
எப்பொழுதும் மனதில் வைத்து கொள்ள

- நேராக நிமிர்ந்து நிற்கவும் அல்லது நிமிர்ந்து உட்காரவும்.
- இன்ஹேலரை பயன்படுத்தும் பொழுது தலையை சற்றே சாய்கவும்.
- வேறு யாரும் உங்கள் இன்ஹேலரை பயன்படுத்த அனுமதிக்க கூடாது.
- வெப்ப ஆதாரங்களில் இருந்து விலக்கி வைக்கவும்.
- உள்ளிழுக்கம் முடிந்ததும் வாயை கழுகவும்.

INHALERS AND SPACER

STEP I:

Assemble the spacer



STEP II:

Shake the inhaler well before use (3-4 shakes)



STEP III:

Remove the cap from your inhaler



STEP IV:

Fit the inhaler into the spacer



STEP V:

Breathe out completely



STEP VI:

Stand straight and tilt head backwards



STEP VII:

Put the mouthpiece **between your teeth** and close your lips



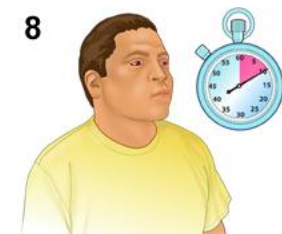
STEP VIII:

Press the top and inhale slowly



STEP IX:

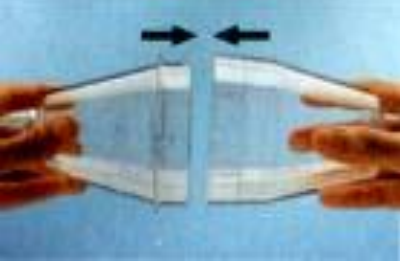
Hold the breath for 10 seconds and slowly exhale



இன்ஹேலர் மற்றும் ஸ்பேசர்

படி I:

ஸ்பேசரை பொருத்த வேண்டும்.



படி II:

பயன்படுத்துவதற்கு முன் இன்ஹேலரை நன்கு குலுக்கவும். (3-4 குலுக்கு)



படி III:

இன்ஹேலரின் மூடியை திறக்கவும்.



படி IV:

இன்ஹேலரை ஸ்பேசரின் உள்ளே பொருத்தவும்.



படி V:

மூச்சை முற்றிலும் வெளியேற்றவும்.



படி VI:

நேராக நின்று, தலையை சிறிதாக சாய்கவும்.



படி VII:

ஊதுகுழலை பற்களின் இடையில் வைத்து வாயை மூடவும்.



படி VIII:

மேற்பகுதியை அழுத்தி, மெதுவாக மூச்சை உள்ளே இழுக்கவும்



படி IX:

10 விநாடிகளுக்கு மூச்சை பிடித்து வைக்கவும், பின் மெதுவாக வெளியேற்றவும்.



HOW TO USE ROTAHALER PROPERLY?

STEP I:

Insert a Rotacap, transparent end first, into the raised square hole of the Rotahaler.



STEP II:

Rotate the base of the Rotahaler



STEP III:

Breathe out completely



STEP IV:

Put the **mouthpiece** between your **teeth** and close your lips



STEP V:

Hold the breath for 10 seconds and slowly exhale



STEP VI:

Continue inhaling if the powder is still there in the Rotahaler

STEP VII:

Remove the Rotacap and dispose.



Always keep in mind:

- Tilt your head back slightly while taking Rotahaler
- Never let anyone else use your Rotahaler.
- Keep your spacer away from heat sources.
- Do not swallow the Rotacaps
- Only insert Rotacaps into the Rotahaler® immediately before using.

ரோட்டாஹேலரை எப்படி சரியாக பயன்படுத்துவது?

படி I:

ரோட்டாகேப்பை (வெளிப்படையான இறுதி) சதுர துளையில் சொருகவும்..



படி II:

ரோட்டாஹேலரின் அடிப்பகுதியை சுழற்றவும்.



படி III:

மூச்சை வெளியேற்றவும்.



படி IV:

உங்களின் பற்களின் இடையே ஊதுகுழலை வைத்து உதடுகளை மூடவும்.



படி V:

10 விநாடிகளுக்கு மூச்சை பிடித்துவைத்து, பின் மெதுவாக வெளியேற்றவும்.



படி VI:

ரோட்டாஹேலரில் பொடி இருக்கும் வரை தொடர்ச்சியாக சுவாசிக்கவும்

படி VII:

ரோட்டாகேப்பை நீக்கி, பின் அப்புறப்படுத்தவும்.



எப்பொழுதும் மனதில் வைத்து கொள்ள

- ரோட்டாஹேலரை பயன்படுத்தும் பொழுது தலையை சற்று பின்புறமாகசாய்கவும்.
- வேறு யாரும் உங்கள் ரோட்டாஹேலரை பயன்படுத்த அனுமதிக்க கூடாது.
- வெப்ப ஆதாரங்களில் இருந்து விலக்கி வைக்கவும்.
- ரோட்டாகேப்பை விழுங்க வேண்டாம்.
- பயன்படுத்துவதன் சற்று முன்புதான் ரோட்டாகேப்பை ரோட்டாஹேலரில் சொருக வேண்டும்.

Annexure 4

Drug Diligence 2017

National Conference & Workshop on Pharmacovigilance

THIS IS TO CERTIFY THAT

Shilz Sandu

HAS PARTICIPATED AS A DELEGATE IN THE EDUCATIONAL ACTIVITY '**DRUG DILIGENCE 2017**'

ORGANIZED & CONDUCTED BY VHEO VENTURES IN KNOWLEDGE PARTNERSHIP WITH OVIYA MEDSAFE PVT LTD

AT IMA HALL, COIMBATORE ON MARCH 17 & 18, 2017.

THIS ACTIVITY HAS BEEN REVIEWED AND ACCEPTED BY THE CENTRE FOR ACCREDITATION, THE TAMIL NADU DR. MGR MEDICAL UNIVERSITY AND THE UNIVERSITY DESIGNATES THIS EDUCATIONAL ACTIVITY FOR A MAXIMUM OF **20 POINTS** IN CATEGORY 3.



DR J VIJAY VENKATRAMAN
MD & CEO, OVIYA MEDSAFE PVT LTD

HONORARY CHAIRPERSON



SURESH S
MANAGER, VHEO VENTURES

ORGANIZING SECRETARY

**PHARMAORATION
2017**



NAZARETH
COLLEGE OF PHARMACY
OTHERA P.O., THIRUVALLA, KERALA - 689546

Certificate

This is to Certify that Mr./Ms./Dr./Prof. SHILZ. SANDU
has participated as a Delegate in One Day National Seminar on "CURRENT TRENDS & OPPORTUNITIES IN
PHARMACEUTICAL FIELD" on 18th February 2017.

Fr. Mathew Kuruvilla
(Manager)

Dr. Elesy Abraham
(Principal & Chair Person)

Dr. Shajan Abraham
(Convenor)